Rimbert v. Eli Lilly & Co.

United States District Court for the District of New Mexico

July 21, 2009, Decided

No. CIV 06-0874 JCH/LFG

Reporter
2009 U.S. Dist. LEXIS 68851; 80 Fed. R. Evid. Serv. (Callaghan) 103; 2009 WL 2208570

MARK GILBERT RIMBERT, individually, and as Personal Representative of the Estates of GILBERT JOHN RIMBERT, and OLIVIA ACOSTA RIMBERT, deceased, Plaintiff, vs. ELI LILLY AND COMPANY, Defendant.

Subsequent History: Affirmed by, Remanded by *Rimbert v. Eli Lilly & Co., 2011 U.S. App. LEXIS 15919 (10th Cir. N.M., Aug. 3, 2011)*

Prior History: *Rimbert v. Eli Lilly & Co., 2008 U.S. Dist. LEXIS 107376 (D.N.M., Sept. 29, 2008)*

Core Terms

suicide, methodology, studies, causation, Depo, depression, reliable, akathisia, epidemiological, serotonin, conclusions, homicide, levels, antidepressant, deposition, scientific, brain, animal, effects, email, homicide-suicide, medications, materials, proffered, patients, ingestion, worsening, appears, chronic, clinical trial

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Judges: JUDITH C. HERRERA, UNITED STATES DISTRICT JUDGE.

Opinion by: JUDITH C. HERRERA

Opinion

MEMORANDUM OPINION AND ORDER

THIS MATTER comes before the Court on Defendant Eli Lilly and Company's ("Lilly's) *Motion to Renew Dispositive and* Daubert *Motions or, in the Alternative, to Certify Orders for Interlocutory Appeal* [Doc. 136, filed November 6, 2008]. This motion seeks to have the Court review and decide anew three motions decided before this trial court was assigned to this case. The Court recently turned its attention to one of those motions--Lilly's [*2] *Motion to Exclude* Expert Testimony of Dr. Grace Jackson [Doc. 58, filed March 20, 2008] and the previous ruling denying that motion [Doc. 125, filed September 29, 2008]. At issue in Lilly's motion is whether the Court should, under the requirements of *Daubert* v. Merrell Dow Pharms., Inc., *509 U.S. 579, 589-98, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993)*, exclude the opinions of Plaintiff Mark Gilbert Rimbert's identified expert, Dr. Grace Jackson. After exhaustively reviewing the motions,

briefs, voluminous exhibits, transcript of oral argument on the issue, and the previous ruling, and being otherwise fully informed, the Court finds that Defendant's motion to renew its Daubert motion and its motion to exclude Plaintiff's expert are both well taken and will be granted. [1]

BACKGROUND

Although the details of this tragic case have been discussed somewhat in prior rulings, the Court will provide this background to help provide context to its ruling. On August 18, 2003, Gilbert Rimbert (″Mr. Rimbert″) consulted his primary care physician, Dr. Barry Hochstadt. Mr. Rimbert paid this visit to his physician during what appears to have been an extremely traumatic point in his life. At age 68, Mr. Rimbert faced the rejection of his wife of 42 years, Olivia, who had informed him of her intent [*4] to seek a divorce approximately three days earlier. *See* Expert Report of Grace Jackson, M.D. (hereinafter ″Report″), attached as Ex. G to Defendant's Memorandum in Support of its Motion to Exclude Expert Testimony (hereinafter ″Def't. Mem.″)[Doc. 59], at 7. Olivia explicitly communicated her intentions to Mr. Rimbert, relatives, and co-workers. *Id*. Her decision to divorce Mr. Rimbert appears to have been motivated by a series of ″small lies,″ financial indiscretions, disagreements about parental obligations toward their youngest son who had chronic problems with substance abuse and criminal behavior, and increasing incompatibility. *Id*.

The impending dissolution of Mr. Rimbert's marriage coincided with several other significant stressors in his life. Mr. Rimbert retired in 1999 and had failed to find meaning in his life following retirement or to achieve satisfying emotional or spiritual connections to others, becoming increasingly lonely and reclusive. *Id* at 6-7, 14, 33. He had incurred approximately $ 40,000 in credit card debt and had seen his 401(k) retirement account shrink from $ 400,000 to approximately $ 40,000. *Id*. at 14. In addition to familial, emotional, and financial stressors, [*5] Mr. Rimbert also suffered from chronic health problems, including obesity, type II diabetes, impotence, hypothyroidism, and acid reflux. *Id*. at 7. In the context of all of these developments, Mr. Rimbert grew increasingly despondent and isolated, and, at the urging of his wife, he consulted Dr. Hochstadt on August 18, 2003. *Id*.

During a brief visit with Mr. Rimbert, Dr. Hochstadt administered and interpreted the Zung Self-Rating Scale for depression, diagnosed a case of moderate depression, and prescribed Prozac at the rate of 20 mg per day. Dr. Hochstadt arranged to see Mr. Rimbert for a follow-up visit in three to four weeks. *Id*. Dr. Jackson's report notes that, according to some of Mr. Rimbert's relatives, he experienced some disturbances in his behavior following his appointment with Dr. Hochstadt, including difficulty sleeping, motor disturbances, and a significant increase in smoking frequency (from one-half pack per day to two packs per day). *Id*. On September 9, 2003, Mr. Rimbert had his follow-up appointment with Dr. Hochstadt. Dr. Hochstadt noted that Mr. Rimbert reported that Prozac ″takes the edge off,″ but also noted the absence of any ″dramatic improvement.″ *See* Deposition [*6] of Dr. Barry Hochstadt,

[1] Previously, the Court stayed activity in this case pending a decision by the United States Supreme Court in *Wyeth v. Levine*, a case addressing whether a state law product liability claim related to drug labeling is preempted by the labeling authority of the Food and Drug Administration. *See* Order Staying Case [Doc. 141, dated December 22, 2008]. The Supreme Court issued its decision in *Wyeth* on March 4, 2009. *See* Wyeth v. Levine, 129 S.Ct. 1187, 173 L. Ed. 2d 51 (2009). [*3] To date, however, the Tenth Circuit has not interpreted the breadth of *Wyeth* with respect to the two cases before it that the Tenth Circuit had stayed pending a decision in *Wyeth*. *See* Dobbs v. Wyeth Pharms., 530 F. Supp. 2d 1275 (W.D. Okla. 2008), Doc. No. 08-6018 (10th Cir. Mar. 7, 2008); Miller v. SmithKline Beecham Corp., 2008 U.S. Dist. LEXIS 16665, 2008 WL 510449 (N.D. Okla. Feb. 15, 2008), Doc. Nos. 08-5042 and 08-5050 (10th Cir. June 4, 2008). The parties have filed extensive briefing concerning the applicability of *Wyeth* to this case. Because the Court's ruling on the Daubert issue is potentially dispositive, it need not resolve the applicability of *Wyeth* to the facts of this case at this time.

attached as Exhibit M to Def't Mem. [Doc. 59] at 57 (hereinafter "Hochstadt Depo."). At neither the follow-up visit nor any other time did Mr. Rimbert report to Dr. Hochstadt any side effects or difficulties related to taking Prozac. *Id*. at 56-57. In response to Mr. Rimbert's reported lack of improvement, Dr. Hochstadt raised the prescribed dose of Prozac to 40 mg per day, and, as he generally did with his depressed patients, cautioned Mr. Rimbert to contact the office if he experienced any suicidality or worsening depression. He also scheduled another follow-up visit for Mr. Rimbert approximately two months later. *Id*. at 62.

Mr. Rimbert never made it to that follow-up appointment. Over the next two weeks, his insomnia, restlessness, and despair intensified. *See* Report at 8. This coincided with a further rejection by his wife and family. Although Mr. Rimbert asked his sons to intercede on his behalf to talk their mother out of divorcing him, they refused, taking their mother's side instead. *See* Deposition of Dr. Grace Jackson (hereinafter "Jackson Depo."), attached as Ex. A to Def't Mem., at 115-116. Further, despite reportedly ceasing gambling and being more **[*7]** attentive to his wife in an effort to convince her not to seek a divorce, such efforts failed. *See* Report at 8. In fact, Mr. Rimbert reportedly told his children and sister that his wife was planning on having him evicted from their home, and gave the impression that she rushed to grab the newspaper each morning in order to show him the public announcement of their impending divorce. *Id*. Finally, on or about the morning of September 25, 2003, Mr. Rimbert shot his wife multiple times with a .38 caliber handgun, killing her, shot and killed his family dog, and then fatally turned the gun on himself. *Id*.

On the dining room table at which the seated Mr. Rimbert shot himself was a handwritten note labeled "assets," Mr. Rimbert's Last Will and Testament, and a suicide note. *Id*. at 10. The suicide note, written on a notepad advertising the tension headache medicine Esgic Plus, said in its entirety: "I know you kids will never be able to forgive me! I love your mother more then [sic] life! We'll be together now for eternity. Love, Dad." *Id*. In addition, the dining room table also had on it a bottle marked "Prozac," although the bottle did not have a pharmacy label, nor did it state Mr. Rimbert's **[*8]** name or contain any other identifying information. *See* Deposition of Yvonne Rimbert, attached as Exhibit J to Defendant's *Memorandum in Support of Motion for Summary Judgment on All Claims* [Doc. 56] at 14-16. [2]

Plaintiff Mark Rimbert, Mr. Rimbert's son, brought this products liability, personal injury, and wrongful death suit against Eli Lilly, the maker of Prozac, alleging that Prozac caused Mr. Rimbert to kill his wife, his dog, and himself. *See* Complaint [Doc. 1]. Plaintiff has designated Dr. Jackson as an expert on "general and specific causation as well as Eli Lilly's failure to warn and/or appropriately test fluoxetine." [3] *See* Plaintiff's Expert Disclosure, attached as Exhibit K to Defendant's *Memorandum in Support of Motion for Summary Judgment on All Claims* [Doc. 56] at 1. In her report, Dr. Jackson stated that Gilbert Rimbert's "overwhelming psychic pain in the face of his spouse's rejection…became **[*9]** obsessive and psychotic…under the influence of Prozac." Report at 52. Her report further concluded:

> I believe it would be incorrect to suggest that Prozac was the necessary and sufficient cause of the deaths of Gilbert and Olivia Rimbert, and their pet dog (Ivy). However, in the context of Gilbert's

[2] Family members also found an unfilled prescription for Prozac written for Mr. Rimbert when they cleaned the home after his death. *See* Deposition of Yvonne Rimbert, attached as Exhibit J to Defendant's *Memorandum in Support of Motion for Summary Judgment on All Claims* [Doc. 56] at 15-17.

[3] Fluoxetine is the generic name for Prozac.

> pre-existing risk factors for suicide and homicide, and in the context of his diminished capacity to resist them, it is more likely than not true that Prozac converted a case of probable dysthymia into a case of agitated depression with obsessive and psychotic features. In this sense, Prozac was the *definitive, contributive* cause of the Rimbert tragedy.

Id. (emphasis in original).

Defendant has moved the Court to exclude Dr. Jackson's expert report and testimony on general causation, specific causation, and proximate causation. Defendant objects based not on Dr. Jackson's conclusions, but rather on the grounds that she is not qualified to express such opinions and because the methodology she used to arrive at her conclusions was flawed. It argues that Dr. Jackson's opinions fail the tests for reliability and relevance set forth by *Rule 702 of the Federal Rules of Evidence*; **[*10]** *Daubert* v. Merrell Dow Pharms., Inc., *509 U.S. at 589-98*; and *Norris v. Baxter Healthcare Corp., 397 F.3d 878, 883-84 (10th Cir. 2005)*. *See* Def't. Mem. [Doc. 59] at 1. The prior trial Court held a Daubert hearing on May 16, 2008, at which the parties argued their respective positions regarding the admissibility of Dr. Jackson's testimony. *See* Transcript of May 16, 2008 Hearing [Doc. 103] at 85-178. [4]

After the Daubert hearing, the prior trial court issued a Memorandum Opinion and Order on the issue of Dr. Jackson's report and ability to testify at trial. *See* Memorandum Opinion and Order, issued September 29, 2008 [Doc. 125]. That Court found **[*11]** that Dr. Jackson's opinions are based on a sufficiently reliable methodology, so it denied Defendant's motion to exclude Dr. Jackson's testimony. Ten days after filing its Daubert ruling, the prior trial court recused itself and the case was transferred to this Court. Following the transfer to this Court, Defendant filed its motion to have this court take a fresh look at, *inter alia*, the prior Daubert ruling.

Defendant cites a number of cases for the proposition that a new trial court is practically obligated to review matters previously ruled on by a recused judge. *See* Defendant's Memorandum in Support of its Motion to Renew [Doc. 137] at 9-11. These cases are inapposite in this instance because they each involve circumstances in which the Court of Appeals either reassigned the case because of evidence of bias or found that, even if the judge in question ultimately recused himself, he waited too long to do so, thereby rendering his decisions untrustworthy. *See, e.g., Clark v. City of Draper, No. 96-4006, 1997 U.S. App. LEXIS 6421, 1997 WL 157382 (10th Cir. April 4, 1997)* (unpublished) (holding that the trial judge should have recused himself early in the litigation, vacating a summary judgment decision, remanding **[*12]** the case to a new judge, and ordering the new judge to reconsider the summary judgment motion); *U.S. v. Franco-Guillen, 196 Fed. Appx. 716, 2006 WL 2879063, at *2-3 (10th Cir. 2006)* (unpublished) (reassigning case to new district court judge, vacating conviction, and ordering proceedings to begin anew where judge's comments in court created an appearance of bias); *U.S. v. Cooley, 1 F.3d 985 (10th Cir. 1993)* (vacating defendants' convictions and sentences and remanding case for new trial before a different judge where the presiding trial judge's statements to the media created an appearance of partiality and judge failed to recuse himself); *Bell v. Chandler, 569 F.2d 556, 560 (10th Cir. 1978)* ("since Judge Chandler should have disqualified himself, and since the cause is to be heard and determined by some other judge, the order for production of documents . . . is hereby vacated.

[4] Although the prior trial court had told Plaintiff that it would not exclude Dr. Jackson's testimony without giving her an opportunity to testify at the Daubert hearing, Plaintiff chose not to have Dr. Jackson testify at the hearing. Because the prior hearing amply covered all of the issues, gave both parties a full opportunity to present their arguments, and addressed any questions that this Court would have, the Court chooses to rely on a transcript of that hearing in to aid it in making its decision, rather than a repeat of the initial hearing.

The request must be determined by the judge assigned to the case."). These issues are not applicable here.

However, even without the showing of bias or any appearance of bias hanging over prior decisions, a successor court has the ability to reconsider the interlocutory orders of their predecessor on the same [*13] case. *See e.g.*, *Been v. O.K. Indus., Inc., 495 F.3d 1217, 1225 (10th Cir. 2007)* (holding that successor judge did not violate the law of the case or abuse his discretion when he reconsidered the ruling of the predecessor district court judge); *Wilson v. Merrell Dow Pharms., 160 F.3d 625, 628 (10th Cir. 1998)* (rejecting plaintiffs' argument that the law of the case foreclosed a subsequent district court judge from granting defendant's motion for summary judgment where the initial judge twice rejected such a motion).

This Court's reconsideration of Defendant's motion to exclude Dr. Jackson's testimony is in no way meant to question the prior trial Court or to imply that the circumstances leading to its recusal affected its decision. Rather, it is simply that this Court must be comfortable that a proposed expert and the methodology on which she bases her opinions is sufficiently reliable such that her testimony will be helpful to the trier of fact. Especially with an issue as discretionary as what evidence is admissible at trial, the trial court must have the ability to decide for itself what evidence to allow. The Court's role as a gatekeeper is necessarily a subjective one. *See Hollander v. Sandoz Pharms. Corp.., 289 F.3d 1193, 1206 (10th Cir. 2002)* [*14] ("when coupled with [a] deferential standard of review, Daubert's effort to safeguard the reliability of science in the courtroom may produce a counter-intuitive effect: different courts relying on essentially the same science may reach different results."). As such, the Court of record has an obligation to use its independent judgment for issues such as expert witness qualification.

LEGAL STANDARD GOVERNING DAUBERT DETERMINATION

The admission of expert testimony is governed by both *Federal Rule of Evidence 702* and that rule's interpretation by the Supreme Court in *Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 589-98, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993)*. Trial courts have the responsibility to ensure that proffered experts will assist the jury in understanding the evidence and in determining the facts at issue. The trial court must not only decide whether a proffered expert is qualified to testify, but also whether the expert's opinion is the product of a reliable methodology. Ultimately, the proponent of the expert testimony bears the burden of establishing by a preponderance of the evidence that the requirements for admissibility have been met. *See United States v. Nacchio, 555 F.3d 1234, 1241 (10th Cir. 2009)* [*15] (en banc); *Ralston v. Smith & Nephew Richards, Inc., 275 F.3d 965, 970 n.4 (10th Cir. 2001)*. The amendment of the Federal Rules of Evidence following the Daubert decision retained the general rule calling for liberal admission of proper evidence. *See United States v. Gomez, 67 F.3d 1515, 1526 (10th Cir. 1995)*; *Fed. R. Evid. 702* advisory committee note. The trial court's proper role "is that of a gatekeeper, a tender or monitor who liberally allows the entrance of proper evidence; it is not a portcullis, excluding qualified patrons for indeterminate reasons." *Nacchio, 555 F.3d at 1280* (Henry, C.J., dissenting).

Under *Rule 702*, the trial court must determine whether the proffered expert is qualified "by knowledge, skill, experience, training, or education" to render an opinion. *Fed. R. Evid. 702*. If the expert is sufficiently qualified, the court must then determine whether the expert's opinion is reliable by assessing the reasoning and methodology underlying the proffered opinion, as set forth in Daubert. Questions concerning reliability may relate to the expert's data, method, or application of the method to the data. *See Fed. R. Evid. 702*; *Mitchell v. Gencorp, Inc., 165 F.3d 778, 782 (10th Cir. 1999)*. [*16] In conducting its

review, the court must focus on ″principles and methodology, and not on the conclusions [generated].″ *Daubert, 509 U.S. at 595*. [5] However, ″conclusions and methodology are not entirely distinct from one another,″ so that ″[a] court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.″ *Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146, 118 S. Ct. 512, 139 L. Ed. 2d 508 (1997)*. That said, even a situation in which a court concludes that an expert's conclusion represents an unfounded extrapolation from the data should result from a focus on methodology rather than on the conclusion itself.

Daubert provides a non-exclusive list of factors that courts may consider in evaluating the reliability of proposed expert testimony: (1) whether the theory can be and has been tested; (2) whether the theory or methodology has been published and subjected to peer review; (3) the known or potential rate of error; (4) the existence of scientific standards and whether the witness followed them; and (5) whether the witness's method is generally accepted as reliable in the relevant medical and scientific community. *Daubert, 509 U.S. at 594-95*. In addition, a court may consider whether the witness's conclusion results from an unfounded extrapolation from the **[*18]** data. *See Joiner, 552 U.S. at 146*. It may look at whether the witness has adequately accounted for alternative explanations for the effect whose cause is at issue. *See Miller v. Pfizer, Inc., 356 F.3d 1326, 1333 (10th Cir. 2004)* (upholding district court's exclusion of expert's testimony on claimed link between the anti-depressant Zoloft and suicidality after finding expert's methodology to be flawed). A court may also take into consideration whether the expert reached her opinion based on research conducted for the purposes of litigation or as the result of independent study. *See Daubert* v. Merrell Dow Pharm., Inc., *43 F.3d 1311, 1317 (9th Cir. 1995)* (excluding testimony on remand from Supreme Court). Under a Daubert analysis, ″any step that renders the expert's analysis unreliable…renders the expert's testimony inadmissible. This is true whether the step completely changes a reliable methodology or merely misapplies that methodology.″ *Nacchio, 555 F.3d at 1241* (quoting *Mitchell v. Gencorp, Inc., 165 F.3d 778, 782 (10th Cir. 1999)* (alteration in original).

DR. JACKSON'S CONCLUSIONS AND METHODOLOGY

Dr. Jackson's report concluded that Gilbert Rimbert's ″overwhelming psychic pain in the **[*19]** face of his spouse's rejection…became obsessive and psychotic…under the influence of Prozac.″ Report at 52. It further concluded that ″it is more likely than not true that Prozac converted a case of probable dysthymia into a case of agitated depression with obsessive and psychotic features. In this sense, Prozac was the *definitive, contributive* cause of the Rimbert tragedy.″ *Id.* (emphasis in original). In her deposition testimony, Dr. Jackson reiterated her conclusion that, ″to a reasonable degree of medical certainty…Prozac contributed to the deaths of Olivia and Gilbert Rimbert.″ Jackson depo. at 359. Finally, Dr. Jackson filed an affidavit just prior to the Daubert hearing that she did not attend, in which she attempted to defend her qualifications and

[5] Plaintiff claims that ″to the best of [his] knowledge, Lilly has lost every single challenge that it has lodged against an expert on general causation grounds in a Prozac-induced violence case,″ and that, therefore, ″it is somewhat astonishing that Lilly would regurgitate its same old arguments again.″ Plaintiff's Memorandum in Opposition to Defendant's Motion to Exclude Dr. Grace Jackson [Doc. 75] at 7-8. Implicit in this statement is the suggestion that, because other courts have found that reports on this subject by other experts have met the threshold of reliability, **[*17]** this Court need not scrutinize the analytical basis of the report offered in this case. While Plaintiff understandably seeks to avoid a close examination of Dr. Jackson's report, following his suggestion would turn the mandated focus on the expert's methodology rather than her conclusion on its head. Under this way of thinking, a proffered expert would be eligible to testify, regardless of the validity of her methodology or quality of her reasoning, as long as her conclusion matched those of experts admitted to testify in other cases.

methodology, as well as to clarify her report's conclusions. *See* Affidavit of Grace E. Jackson, M.D., filed May 22, 2008, [Doc. 99]. Her affidavit maintained that her original report and testimony were consistent in supporting the conclusion that ″Prozac [was] the linchpin of the Rimbert tragedy.″ *Id*. at 4. Dr. Jackson also argued that ″[i]t was against a complex backdrop of personal and familial circumstances, but within a progressive **[*20]** chain of events, that Prozac proved to be the clincher.″ *Id*.

A. General Causation

In forming her conclusion on general causation, Dr. Jackson relied on two peer-reviewed scientific papers to support her opinion that Prozac has a ″propensity … to induce suicidality.″ Report at 35. The two papers she cited are the ″Cusin article,″ [6] and the ″Perlis article.″ [7] Dr. Jackson claims that the two complementary papers ″reveal the astoundingly high prevalence of suicide and worsening of depression during the early course of treatment.″ *Id*. The Cusin article is based on a retrospective review of a database culled from a pre-1998 multi-center study. The Cusin analysis involved, after exclusions, 694 participants who were placed on 20 mg/day of Prozac for twelve weeks. The authors of the study observed ″clinical worsening″ -- in other words, increased depression -- in 30% of participants. [8] *Id*. at 36.

The Perlis article is another retrospective review of the same database that provided the basis for the Cusin study. *Id*. at 37. That paper showed that, after three months, 14% of participants who started Prozac therapy without suicidal tendencies had experienced an onset of suicidality at some point during the treatment phase. *Id*. at 38. In her report, Dr. Jackson noted that the authors of the Perlis article applied a ″Cox regression model″ to demonstrate that ″activiation (agitation, nervousness, and/or akathisia) and early clinical worsening were both significantly associated with **[*22]** the emergence of suicidality.″ *Id*.

The second component of Dr. Jackson's general causation analysis is her linking of Selective Serotonin Reuptake Inhibitors (″SSRIs″) [9] to akathisia [10], and the further potential connection of akathisia to dysphoria, irritability, aggression, or suicide attempts. *See id*. at 39. Dr. Jackson contends in her report that SSRIs may cause akathisia, and that akathisia could, in turn, cause aggression and suicidality. She cites the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition--Text Revision* (American Psychiatric Society, 2000) (″DSM IV″) to support her contention. *See* Report at 39 (citing DSM IV at 801 for proposition that ″Akathisia may be associated with dysphoria, irritability, aggression, or suicide attempts….Serotonin-specific reuptake inhibitor antidepressant medications may produce akathisia that appears to be identical in phenomenology and treatment response to Neuroleptic-Induced Acute Akathisia.″). Dr. Jackson concludes, without citation to any source,

[6] C. Cusin, M. Fava, J.D. Amsterdam, F.M. Quitkin, F.W. Reimherr, C.M. Beasley, Jr., J.F. Rosenbaum, and R.H. Perlis, *Early Symptomatic Worsening During Treatment With Fluoxetine in Major Depressive Disorder: Prevalence and Implications*, 68:1 J. Clinical Psychiatry 52-57 (2007). Attached as Exhibit E **[*21]** to Def't. Mot. [Doc. 59].

[7] R.H. Perlis, C.M. Beasley, Jr., J.D. Wines, Jr., R.N. Tamura, C. Cusin, D. Shear, J. Amsterdam, F. Quitkin, R.E. Strong, J.F. Rosenbaum, and M. Fava, *Treatment-Associated Adverse Effects in an Open, Multicenter Trial of Fluoxetine for Major Depressive Disorders*, 76 Psychotherapy & Psychosomatics 40-46 (2007). Attached as Exhibit F to Def't. Mot. [Doc. 59].

[8] By incorporating data from patients whom the study's authors deliberately omitted for methodological reasons, Dr. Jackson calculated that the number of patients who deteriorated while on Prozac actually reached 39%. Report at 36.

[9] SSRIs are a family of antidepressant medications, of which Prozac is a member.

[10] Akathesia is a neurological condition consisting of two components: (1) an inner, subjective, feeling of restlessness or needing to move; and (2) an observable, outward manifestation of psychomotor activation, such as hand-wringing, the inability to remain seated, or constant movement. *See* Jackson depo at 144.

that ″it is essential for clinicians to recognize the possibility that suicide and/or homicide may become attractive 'solutions' to the *unrelenting psychic distress* of [*23] akathisia.″ *Id*. (emphasis in original).

B. Specific Causation

In order to arrive at her opinion on specific causation, Dr. Jackson explored three factors: (1) Pharmacodynamics -- what Prozac does to the brain, (2) Pharmacokinetics -- what the body does to Prozac, and (3) Unique biology -- how Mr. Rimbert's physiology could have contributed to Prozac's effect on him. In reaching her conclusion, Dr. Jackson relied on human and animal studies, as well on extrapolations based on her knowledge of the chemical components of SSRIs.

In characterizing the pharmacodynamics of Prozac, Dr. Jackson contends that ″a substantial number of investigations imply that Prozac and other [SSRIs] would be well characterized as substances which induce a state of *serotonin insufficiency*.″ Report at 40 (emphasis in original). [*24] In support of this statement, she cites several studies that looked at levels of neurotransmitter metabolites within cerebrospinal fluid as a proxy for intercranial events (because the collection of actual neurotransmitters from the living human brain is a practical impossibility). Dr. Jackson characterized these studies as ″universally demonstrat[ing] that [SSRIs]--in patients and healthy controls--trigger a significant and prolonged reduction in the serotonin metabolite known as 5HIAA.″ *Id*. She indicates that the sustained reduction of 5HIAA ″has been shown to reflect a decrease in serotonin turnover (i.e., less serotonin breakdown *because of* diminished serotonin production and release.″ *Id*. (emphasis in original). Further, Dr. Jackson maintains that ″low levels of 5HIAA have been consistently found in the cerebrospinal fluid of patients and perpetrators of impulsive acts, including arson, homicide, and suicide,″ although she does not indicate whether the research she cites purports to establish causation or merely identifies correlation. *Id*.

Dr. Jackson also cites several animal studies that corroborate this phenomenon and concludes that SSRIs in general ″appear to induce a long-lasting [*25] vulnerability within the serotonin pathways of the brain--a perturbation which likely increases the risk of chronic and/or recurrent depression and anxiety.″ *Id*. at 46. She goes on to cite other animal studies that demonstrate that acute exposure to SSRIs results in reduced firing rates of serotonin and dopamine neurons, which may account for akathisia and other side effects that can lead to aggression and suicide. *Id*.

Pharmacokinetics refers to how the body absorbs, distributes, metabolizes, and excretes a drug. Dr. Jackson suggests that the way Prozac is absorbed by the body makes it more likely to concentrate in certain patients. In discussing Prozac's pharmacokinetic profile, Dr. Jackson explains that Prozac has a relatively longer half-life than many other SSRIs, and this can delay the emergence of certain drug effects. *Id*. at 47. Second, she points out that ″[f]or the '7% of the population' who might be poor metabolizers of drugs cleared by [a particular enzyme], Prozac…may accumulate to higher than normal levels.″ *Id*. Third, Dr. Jackson believes that the fact that Prozac is considered to be an inhibitor of certain enzymes ″suggest[s] that Prozac may provoke or exacerbate drug-drug [*26] interactions.″ *Id*. Finally, she notes that, because Prozac is a medication that is primarily metabolized by the liver, any liver pathologies can prolong the drug's half-life, boosting the potential for adverse effects. *Id*.

Using her knowledge of Prozac's pharmacokinetic profile, Dr. Jackson then advanced several theories on how Prozac could have affected Mr. Rimbert. She first noted that Mr. Rimbert would have been at increased risk for accumulating higher than normal levels of Prozac if he was among the small

percentage of people who are poor metabolizers of drugs cleared by the 2D6 enzyme system, but acknowledged that she did not know if he was among that population. *Id*. at 48. She then asserted that, even without this genetic predisposition, Mr. Rimbert might have been vulnerable to higher than expected levels of Prozac in his blood and brain under several possible circumstances. For instance, if he had been taking Zantac for heartburn at the same time he took Prozac, this could potentially have caused an atypical accumulation of Prozac levels, although it is unknown whether he was, in fact, taking Zantac after initiating Prozac treatment. *Id*. Alternatively, Mr. Rimbert ″may have″ **[*27]** accumulated Prozac at an atypical level through the interaction of the medications for which he had prescriptions at the time of his death, as these medications could have competed for clearing by the 3A4 enzyme. *Id*. ″Although 3A4 is considered to be a 'high capacity' system, and although none of [Mr. Rimbert's] medications are characterized as potent disruptors of 3A4 function, there remains the possibility that these agents were nevertheless capable of 'nudging' each other aside when vying for the same binding site.″ *Id*. Additionally, a fatty liver, such as an autopsy revealed that Mr. Rimbert had, enhances the risk of drug toxicity by impeding the process of drug metabolism and elimination. *Id*. Finally, Dr. Jackson surmised that Mr. Rimbert's pre-existing hypothyroidism, diabetes, and high cholesterol, and their accompanying treatments, could have increased the risk of Prozac-induced or enhanced depression and violence. *Id*. at 49-50.

Dr. Jackson made these pharmacokinetic suppositions despite the fact that Mr. Rimbert's postmortem blood sample revealed ″normal″ levels of Prozac and its metabolite, rather than elevated levels. *Id*. at 50. She suggested that Mr. Rimbert could have shown **[*28]** a normal level of Prozac in his blood, despite actually being exposed to dangerous levels, because smoking could have reduced the level that showed up in the test, or because it is possible that he reduced, skipped, or stopped taking Prozac in the days before the shooting. *Id*. Alternatively, Dr. Jackson argues, Mr. Rimbert's pre-existing medical conditions and associated treatments could have increased his sensitivity to the effects of Prozac, so that even normal concentrations of the drug could have led to lethal effects. *Id*.

Based on this methodology, Dr. Jackson concluded that ″in the context of [Mr. Rimbert's] pre-existing risk factors for suicide and homicide, and in the context of his diminished capacity to resist them, it is more likely than not true that Prozac converted a case of probable dysthymia into a case of agitated depression with obsessive and psychotic features.″ *Id*. at 52. Dr. Jackson considered Mr. Rimbert's psychic pain under the influence of Prozac to be obsessive because he ″became exclusively focused upon preventing his wife's departure from the marriage.″ *Id*. She considered it to be psychotic in the sense that he ″developed a death fantasy in which he came to **[*29]** view murder and suicide as a means of reuniting with Olivia eternally, in the afterlife,″ which ″was highly irrational, in the sense that murder was hardly an expression of how much he 'loved' his wife.″ *Id*. In her opinion, this ″death fantasy″ was also delusional, ″in the sense that it violated his faith's proscriptions against murder and suicide, through which the perpetrator's soul would presumably be condemned to hell (*not* the destination of [Mr. Rimbert's] innocent victims).″ [11] *Id*. (emphasis in original). In Dr. Jackson's opinion, because Prozac elevated Mr. Rimbert's moderate depression into an agitated depression with obsessive and psychotic features, it ″was the *definitive, contributive* cause of the Rimbert tragedy.″ *Id*. (emphasis in original).

ANALYSIS

[11] Presumably, in making this assessment of the theological flaw in Mr. Rimbert's plan, Dr. Jackson was referring to the fact that Mr. Rimbert was raised Catholic, despite his having fallen away from church attendance in the decades prior to this tragic incident.

A. Witness Qualification

Defendant challenges Dr. Jackson's qualifications as an expert on the grounds that she lacks the objectivity necessary to make her opinions scientifically [*30] valid and that she has no expertise in the causation of homicide-suicide. [12] Defendant's objectivity argument is twofold: Dr. Jackson worked exclusively for Plaintiff's counsel's law firm, and she formed conclusions about the case prior to doing any research or even knowing the full facts about the case.

At the time she received the assignment to write her report in this case, Dr. Jackson had been a full-time employee of Plaintiff's law firm for approximately nine months, and she remained a full-time employee of the firm during the time she wrote the opinion. *See* Deposition of Dr. Grace Jackson in *Gruder v. Smithkline Beecham Corp*., taken Dec. 11, 2007 (hereinafter "Other Jackson Depo."), attached as Ex. B to Def't Mem., at 61, 250. Defendant argues that Dr. Jackson's response to an email she received regarding the Rimbert case further illustrates her lack of objectivity. Dr. Jackson apparently first learned of this case in a September 5, 2007 e-mail from Plaintiff's attorney's secretary, which states:

Grace:

Pros: It's a murder-suicide. Man was on Prozac, shot his wife, his dog and then himself. Need report.

Cons: Report due 9/24/07.

Are you up for it?

E-mail from Karin [*32] Shepherd, Secretary to Plaintiff's attorney (Mr. Vickery), to Dr. Jackson regarding *Rimbert v. Eli Lilly* (dated September 5, 2007), attached as Exhibit C to Def't Mot.

Approximately six hours later, apparently knowing nothing about the case other than the information she received in the earlier e-mail, [13] Dr. Jackson responded: "That sounds like an EXCELLENT case." E-mail from Dr. Jackson to Karin Shepherd (dated September 5, 2007), attached as Exhibit D to Def't Mot. Defendant claims that this email response demonstrates that Dr. Jackson knew what Plaintiff was asking her to do (demonstrate that Prozac was responsible for the death of Mr. Rimbert, his wife, and his dog), and that, without any further information, Dr. Jackson agreed to make that finding. In other words, that, as a full-time employee of Plaintiff's counsel's firm, she would attempt to reason backwards to justify the conclusion she was being asked to reach. Certainly, Dr. Jackson's response and the

[12] Plaintiff also sought to have Dr. Jackson testify on the adequacy of the warnings accompanying Prozac at the time it was prescribed for Mr. Rimbert. Defendant challenged her qualifications to opine on this subject on the grounds that she has no training in prescription drug labeling, that she has no experience in drafting warnings, that she did not draft a proposed adequate warning in this case, and that she admitted in her deposition that she is not qualified to say what would constitute an adequate warning. Because the Court has determined that Dr. Jackson may not testify regarding a general or specific causal link between Prozac and homicide/suicide, it need not reach the issue of Dr. Jackson's qualifications to opine on warnings. "If the jury will hear no evidence that [Prozac] causes suicide [and homicide], it cannot possibly conclude that [Prozac] labels do not adequately warn [*31] against the danger that [Prozac] causes suicide [and homicide]." *Miller v. Pfizer, Inc*., 196 F. Supp. 2d. 1062, 1089 (D. Kan. 2002), *aff'd* 356 F.3d 1326 (10th Cir. 2004). Thus, even if she were qualified to offer testimony on the adequacy of warnings, such testimony would not be relevant to any material issue in the case.

[13] Perhaps in an effort to counter Defendant's accusation that Dr. Jackson's email revealed her to be less than objective, Plaintiff's counsel claimed in his response to Defendant's motion to exclude Dr. Jackson's testimony that "Dr. Jackson obtained additional information about the facts [prior to sending her email] from her conversations with counsel." Pl. Resp. at 4. Plaintiff's counsel supported this assertion by attaching a sworn declaration to the response, in which he testified: "I had discussed the facts of the case with her on an informal basis prior to the initial email which is cited in Lilly's motion papers." Declaration of Andy Vickery, dated April 17, 2008, attached as [*34] Ex. E to Pl. Resp. at 3. Aside from the questionable propriety of counsel inserting himself into the proceedings as a fact witness, the Court notes that counsel directly contradicts the sworn testimony of his proffered expert. *See* Jackson Depo. at 272-73 (testifying that the sum and substance of her knowledge of the Rimbert case came from Karin Sheperd's email to her).

circumstances surrounding it could be cause for calling into question her credibility. However, the Court believes that such credibility challenges are more properly saved for cross examination and such credibility determinations [*33] are more properly the province of the trier of fact. The Court's ruling today is based solely on its determination that the methodology Dr. Jackson used to reach her opinion rendered her conclusions unreliable. While ″coming to a firm conclusion first and then doing research to support it is the antithesis of [the scientific] method,″ *Claar v. Burlington N. R.R. Co., 29 F.3d. 499, 502 (9th Cir. 1994)*, the Court's ruling is in no way meant to suggest that it finds that Dr. Jackson proceeded in this manner.

Defendant also contends that, because this case involved a homicide linked to a suicide, only someone who is an expert in the specific phenomenon of homicide-suicide is qualified to opine on the cause of this tragic case. Dr. Jackson does not claim to be an expert on homicide-suicide. Jackson depo. at 59. Dr. Jackson is aware that a body of published medical literature exists regarding the unique phenomenon of homicide-suicide, but she has not studied that literature. *See id*. at 60:17-61:15, 139:13-18. Other than ″skimming abstracts,″ Dr. Jackson did not read any articles on homicide-suicide while formulating her causation opinions in this case because of ″time constraints in the production of her report.″ *Id*. at 60:17-61:15. Dr. Jackson does not know whether the recognized risk factors for homicide-suicide are the same [*35] as those for an isolated homicide, about the different types of homicide-suicide, or whether there are different risk factors for different types of homicide-suicide. *See id*. at 139:2-12, 140:3-17. Specifically, Dr. Jackson cannot opine about the relevance of a history of prior violence or domestic violence as a risk factor for different types of homicide-suicide, because she has not researched these issues in the medical literature. *See id*. at 141:2-11.

The Court finds that familiarity with the discrete literature of homicide-suicide is not a prerequisite to offering testimony on causation in a case such as this. Dr. Jackson is a board-certified psychiatrist with experience treating patients, prescribing anti-depressants, and studying the effects of medication on the brain and body. While Defendant could make the argument to a jury that failure to familiarize herself with literature on the specific phenomenon of homicide-suicide weakens her report, the Court finds that Dr. Jackson has sufficient ″knowledge, skill, experience, training, [and] education″ in her field to qualify as an expert. *Fed. R. Evid. 702*.

B. General Causation

1. Human Studies

In her report, Dr. Jackson cites only two [*36] studies of Prozac in humans, which she characterizes as ″reveal[ing] the astoundingly high prevalence of suicide and worsening of depression during the early course of treatment.″ Report at 35. However, these studies, the Cusin paper (attached as Exhibit E to Def't. Mot. [Doc. 59]) and the Perlis paper (attached as Exhibit F to Def't. Mot.), are of limited use in supporting a valid scientific conclusion because all of the data on which the papers are based is uncontrolled. In other words, there is no ″placebo control arm″ -- or group not taking Prozac -- to compare to the group of patients who were taking Prozac. Jackson Depo. at 183:25-184:22; *id*. at 196:2-7. The authors of the Cusin and Perlis articles recognize the limitations inherent in their studies caused by the lack of control groups. *See* Cusin article at 56 (″The major limitations of the present study are the post hoc nature of the analyses and the absence of a placebo double-blind control.″); Perlis article at 45 (″A second limitation in the present study is the absence of a placebo or active comparator group.″).

The lack of a control group makes it impossible to state whether the adverse events observed were a

result of Prozac, [*37] part of the natural history and fluctuations of depression, or caused by other factors. *See* Cusin article at 55 (″Worsening may have different possible explanations. For example, worsenings during the first few weeks of treatment may not be etiologically related to antidepressant therapy, but may simply represent a correlate of the natural history of the disease.″); *id*. (″Worsening may be a secondary to stressful life events. . . .″); Perlis article at 45 (″It is thus impossible to establish a specific association between fluoxetine and treatment-emergent adverse events.″); Jackson Depo. at 185:24-186:5; *id*. at 197:12-198:3. Dr. Jackson admitted that, because neither study had a control group, one cannot draw a scientifically valid conclusion, from either paper, as to whether Prozac caused or was even associated with the observed adverse events reported, whether worsening of depression in the Cusin article or suicidal thinking in the Perlis article. *See* Jackson Depo. at 195:7-20; *id*. at 201:17-202:10.

Suicide, homicide, and homicide-suicide occur in the general population, specifically in individuals who are not taking Prozac or any other antidepressant. Without controlled data, there [*38] is no way to know whether such events are more common in depressed patients taking Prozac than in depressed patients not taking Prozac or any antidepressant drug. *See, e.g., In re: Breast Implant Litigation, 11 F.Supp.2d 1217, 1224 (D. Colo. 1998)* (″Without a controlled study, there is no way to determine if those symptoms are more common in women with silicone breast implants than women without implants.″); *Reference Manual on Scientific Evidence* at 95 (Federal Judicial Education Center 2d ed. 2000) (″Was there a control group? If not, the study has little to say about causation.″).

2. Animal Studies

Dr. Jackson also bases her conclusion on several studies conducted on animals -- namely, monkeys and rats. *See* Report at 41-44. Dr. Jackson contends that the cited animal studies demonstrate that Prozac reduces the level and activity of neurotransmitters in the brain (serotonin and dopamine), ″believed to account for akathisia and other side effects which can lead to aggression and suicide.″ *Id*. at 46. She also contends that the cited studies show that SSRIs ″eventually reduce the brain's supply of releasable serotonin,″ and that ″animals exposed to SSRIs have…a [*39] 50-70% depletion of serotonin.″ *Id*.

Two of the studies on rat brains that Dr. Jackson cites, including one that she represents to be a study of Prozac, did not study Prozac at all, but instead studied the effects of chemically distinct SSRIs (Paxil, Zoloft, and Luvox). [14] Dr. Jackson admits that her report is in error on that point. *See* Jackson Depo. at 317:3-6, 319:11-25.

Another animal paper cited by Dr. Jackson, the Smith study, [15] investigates the effect of chronic administration of Prozac on the brains of monkeys. As admitted by Dr. Jackson, this paper actually contradicts her contention that Prozac reduces the level and activity of serotonin and dopamine in the brains of monkeys. *See* Other Jackson Depo

[14] *See* M. Di Mascio, G. Di Giovanni, V. Di Matteo, S. Prisco, and E. Esposito, *Selective Serotonin Reuptake Inhibitors Reduce the Spontaneous Activity of Dopaminergic Neurons in the Ventral Tegmental Area*, 46:6 Brain Research Bulletin 547-54 (1998)(reference number 36 in Report and attached as Exhibit I to Def't Mem.) (study involving the intravenous administration of progressively increasing doses of paroxetine [Paxil], sertraline [Zoloft], and fluvoxamine [Luvox]); F. Yamane, H. Okazawa, P. Blier, and M. Diksic, *Reduction in Serotonin Synthesis Following Acute and Chronic Treatments With Paroxetine, a Selective Serotonin Reuptake Inhibitor, In Rat Brain: An autoradiographic study with alpha-[14C]Methyl-l-tryptophan*, 62 J. Biochemical Pharmacology 1481-89 (2001)(reference number 37 in Report and attached as Exhibit [*40] J to Def't Mem.) (study involving paroxetine [Paxil]).

[15] T. Smith, R. Kuszenski, K. George-Friedman, J.D. Malley, & S.L. Foote, *In Vivo Microdialysis Assessment of Extracellular Serotonin and Dopamine Levels in Awake Monkeys During Sustained Fluoxetine Admininstration*, 38 Synapse 460-70 (2000)(reference number 31 in Report and attached as Exhibit K to Def't Mem.).

(attached as Ex. B to Def't Mem.) at 331:18-21, 333:15-25 (conceding that chronic administration of Prozac did not result in a statistically significant decline in dopamine levels in the brain's caudate and that the monkeys' serotonin levels were no lower after prolonged treatment with Prozac than before treatment began).

Dr. Jackson also concedes that there are substantial differences between the brains of animals and those of human beings in response to the administration of antidepressants. [*41] *See* Other Jackson Depo. at 323:14-21. Dr. Jackson performed no calculations to determine whether the dose or route of administration of antidepressants to rats and monkeys in the papers that she cited in her report was equivalent to or substantially similar to human beings taking prescribed doses of Prozac. *See* Jackson Depo. at 322:13-23. Comparability of dosage appears especially important to assessing the methodology's reliability when conclusions about what can happen to humans, and what did happen in this case, are based on animal studies and not replicated by controlled human studies.

The three studies cited by Dr. Jackson that use postmortem analysis of rat brain tissue following chronic Prozac administration rely on dosages between 10mg/kg per day and 30 mg/kg per day. *See* Report at 44. A comparable dosage for someone of Mr. Rimbert's weight would have been between approximately 750 mg/day and 2250 mg/day rather than the 20 mg/day dosage that he was initially prescribed, which Dr. Hochstadt later increased to 40 mg/day. In other words, the dosages given the rats in the studies cited by Dr. Jackson to establish the effect of chronic Prozac ingestion on serotonin and dopamine levels [*42] was between 37 and 112 times higher than Mr. Rimbert's initial prescription, and between 19 and 56 times the increased dosage he was prescribed in the two weeks prior to his death. [16] Dr. Jackson's report contained no discussion concerning comparability of dosage or the applicability of high-dose animal studies to the low-dose effect on humans, making the reliability of conclusions based on such studies open to question. *See* *Hollander v. Sandoz. Pharms. Corp., 289 F.3d 1193, 1209 (10th Cir. 2002)* (upholding district court's conclusion that certain animal studies, including those involving much larger doses of the drug in question than that ingested by the subject of the opinion, were unreliable in establishing causation).

Dr. [*43] Jackson agrees that the animal studies that she cited in her report merely create hypotheses about what might happen in humans. See Jackson Depo. at 266:23-270:2; Other Jackson Depo. at 324:19-325:20. She admits that any of the effects discussed in the animal papers that she cites remain unproven because the testing methodologies used by the authors of those papers have not or cannot be conducted on humans with present technology and that, therefore, one cannot draw a scientifically valid conclusion about what actually happens in humans based on the animal studies. *See* Jackson Depo. at 268:3-270:3; Other Jackson Depo. at 325:1-20. An untested hypothesis does not provide a scientifically reliable basis for an opinion on causation. *See* *Norris v. Baxter Healthcare Corp., 397 F.3d 878, 882 (10th Cir. 2005)*; *In re: Breast Implant Litigation, 11 F.Supp.2d at 1228*.

3. Epidemiological Evidence

Epidemiological studies are the best evidence of causation in a case such as this, in which exposure to a substance is alleged to have caused injury. *See* *Norris, 397 F.3d at 882*; *In re: Breast Implant*

[16] Dr. Jackson's report cites the Medical Examiner's report to establish that, at the time of his death, Mr. Rimbert weighed approximately 166 pounds. *See* Report at 26. 166 pounds correlates to approximately 75 kilograms, using a conversion factor of 2.2 pounds per kilogram. Thus, a dosage of 10mg/kg per day would work out to approximately 750 mg/day for someone of Mr. Rimbert's weight, while a dosage of 30mg/kg per day would work out to approximately 2250 mg/day.

Litigation, 11 F.Supp.2d at 1228. [17] In attempting to prove that exposure to a substance caused an injury, [*44] "a 'lack of epidemiologic studies supporting [a plaintiff's] claim creates a high bar for [a plaintiff] to surmount with respect to the reliability requirement." *Farris v. Intel Corp., 493 F. Supp. 2d 1174, 1181 (D. N.M. 2007)* (quoting *Siharath v. Sandoz Pharms. Corp.., 131 F. Supp. 2d 1347, 1358 (N.D. Ga. 2001)*, *aff'd 295 F.3d 1194 (11th Cir. 2002))* (alterations in original). A controlled clinical study, a type of epidemiological study in which one group of subjects is exposed to the agent of interest and the other group is not exposed, "is considered the gold standard for determining the relationship of an agent to a disease or health outcome." *Reference Manual on Scientific Evidence* at 338 (Federal Judicial Education Center 2d ed. 2000).

Dr. Jackson's report does not contain any citation to any controlled clinical trial or other epidemiological study which demonstrates that the ingestion of Prozac creates an increased risk or an increased incidence of the following conditions: akathisia, suicidal thinking, suicidal behavior or completed suicide, violence or homicidal behavior, worsening depression, psychotic decompensation, psychiatric rage, impulsivity or impulsive behavior, or disinhibition or diminished capacity to resist engaging in homicidal or suicidal behavior. Nor did she rely on any such studies, to the extent any existed, in forming her opinion. *See* Jackson Depo. at 163:24-166:9; *id*. at 170:14-171:13; *id*. at 173:24-174:24; *id*. at 250:7-14; *id*. at 251:7-11.

Even more damaging to Dr. Jackson's reliability than her lack of [*46] reliance on epidemiological studies to generate and support her conclusions is her failure to grapple with any of the myriad epidemiological studies that refute her conclusion. At the time she wrote her report, Dr. Jackson was aware of a body of published medical and scientific literature, including controlled clinical trials and other epidemiological studies, which supports the proposition that Prozac is not associated with suicidality, but she did not consider that literature in the formation of her opinions and report in this case. *See* Jackson Depo. at 66:11-21. Additionally, when she wrote her report in this case, Dr. Jackson was aware that the FDA had reported to the public and to medical communities the results of its analysis of controlled clinical trials of antidepressants, including Prozac, and its conclusions that ingestion of antidepressants, including Prozac, creates no increased risk of suicidality in adults over twenty-four years of age and results in a *decreased* risk of suicide in individuals over the age of sixty-five. [18] *See id*. at 174:25-177:9. Dr. Jackson also does not dispute the FDA's interpretation and analysis of the controlled clinical trial data, and has not

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[17] *Norris* stated that epidemiological studies are the best evidence of causation in a "toxic tort" case, but it did not define "toxic tort." The term "toxic tort" refers to circumstances under which plaintiffs attempt to prove that they suffered harm as a result of exposure to a substance. The Court is not aware of a widely-accepted definition that limits the term to cases involving substances that are harmful in all instances. Thus, the term would seem [*45] to allow for a wide variety of cases, ranging from exposure to harmful external substances, such as asbestos or nuclear material, to the adverse affects of substances deliberately ingested into the body, including prescribed medicines. Nonetheless, the Court need not decide the exact contours of a "toxic tort" to find that the principle that the *Norris* court articulated applies in this case.

[18] The current FDA-approved label for Prozac reflects the FDA's conclusions from its analysis of antidepressant controlled clinical trials. It states:

> Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder and other psychiatric disorders. Anyone considering the use of Prozac or any other antidepressant in a child, adolescent, [*48] or young adult, must balance this risk with the clinical need. *Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older*. Depression and certain psychiatric disorders are themselves associated with increases in the risk

[*47] analyzed the data on which the FDA relied in coming to its conclusions. *Id*. at 175:10-177:9. Nor did she examine the controlled clinical trial data examining the issue of whether Prozac causes suicide, despite being aware of its availability. *Id*. at 203:10-15. There are numerous peer-reviewed publications on controlled clinical trials, meta-analyses of controlled clinical trials, and other epidemiological studies that support the proposition that Prozac and other SSRIs are not associated with suicidality or violent, aggressive behavior. *See, e.g.*,Exhibit N to Def't Mem. (containing a bibliography listing fourteen articles regarding meta-analyses of controlled clinical trials with Prozac, other SSRIs, and other antidepressants).

The Tenth Circuit made clear its view of the value of epidemiological studies in *Norris*, stating that ″where there is a large body of contrary epidemiological evidence, it is necessary to at least address it with evidence that is based on medically reliable and scientifically valid methodology.″ *Norris, 397 F.3d at 882*. The *Norris* court went on to hold that ″[w]hile the presence of epidemiology does not necessarily end the inquiry, where epidemiology is available, it cannot be ignored. As the best evidence of general causation, it must be addressed.″ *Id*. Fatally for her reliability, rather than accounting for any of the many contrary epidemiological studies that showed no medically [*49] reliable link between Prozac and homicide/suicide in the target population in reaching her conclusion or writing her report, Dr. Jackson did not address them or discounted them without explanation. As a consequence, the methodology she used to reach her conclusion is ultimately unreliable, as ″[n]on-epidemiological studies, singly or in combination, are not capable of proving causation in human beings in the face of an overwhelming body of contradictory epidemiology evidence.″ *Id. at 887 n.8* (internal quotation marks and brackets omitted). [19]

Of course, an expert cannot be expected to anticipate all attacks on her report or to move preemptively to counter them, nor must [*50] she consider and discuss all relevant literature and evidence. The Court is aware of the liberal standard under which scientific evidence should be admitted, and is not looking for such a Herculean effort on the part of a proffered expert. Indeed, in an attempt to rebut criticism of Dr. Jackson's report, Plaintiff's counsel has cited many studies upon which Dr. Jackson could have relied. Unfortunately, however, she did not do so prior to reaching her conclusions, and to ignore completely the vast body of contradictory evidence, and especially to refuse to engage with contrary epidemiological studies while offering no supporting studies in return, strikes at the heart of a proffered expert's reliability.

4. Departure from Standard Methodology

Courts have excluded experts' opinions when the experts depart from their own established standards or the standards followed in their field. *See Truck Ins. Exch. v. Magnetek, Inc., 360 F.3d 1206, 1213 (10th Cir. 2004)* (″The district court noted that [the expert]'s opinion did not meet the standards of fire investigation [the expert] himself professed he adhered to.″); *Magdaleno v. Burlington N. R.R. Co., 5 F.Supp.2d 899, 905 (D.Colo. 1998)*(″In sum, [*51] [the expert]'s methodology is not consistent with the methodologies described by the authors and experts whom [the expert]

of suicide.

FDA-approved label for Prozac, revised June 21, 2007, attached as Exhibit L to Def't Mem. (emphasis added).

[19] In using this quotation, the Court does not intend to suggest that no epidemiological studies exist that demonstrate some connection between Prozac and suicidality in some people, or that the evidence against such a link is ″overwhelming.″ Instead, it merely uses it as an illustration that an expert who chooses to completely ignore significant contrary epidemiological evidence in favor of focusing solely on non-epidemiological studies that support her conclusion engages in a methodology that courts find unreliable.

identifies as key authorities in his field."). Dr. Jackson testified that, in order to assess strength of association and whether a drug actually caused a specific adverse event rather than simply having an association with the event, experts in the areas of epidemiology and pharmaco-vigilance utilize the criteria set forth by Sir Austin Bradford Hill. [20] *See* Other Jackson Depo. at 76:22-77:5; Jackson Depo. at 154:16-20. In fact, Dr. Jackson not only testified that the Hill criteria are generally accepted in her field, but she also asserted that she personally embraced that approach. *See* Other Jackson Depo. at 255:8-11 ("Q: And how do you assess, as a general methodologic matter, whether it's association or causal? A: Again, I go through the Hill criteria."). However, despite her recognition of these widely-accepted criteria, and her personal embrace of the methodology, Dr. Jackson inexplicably did not apply the Hill criteria to reach or test any of the conclusions in her report. *See* Jackson Depo. at 155:8-10 ("Q: Yeah, you didn't use Bradford Hill criteria [sic] **[*52]** in formulating your opinion in this case, did you? A: No. I did not."). That Dr. Jackson chose not to apply the methodology that she personally considers to be the standard in her field to assess causation undermines the reliability of her testimony.

Dr. Jackson also testified that she "intuitively" followed the general scientific method in formulating her opinions in this case, consisting of five steps: (i) generating a hypothesis; (ii) formulating a plan of investigation or protocol regarding **[*53]** the procedure for data gathering and data analysis; (iii) gathering data following the protocol procedures; (iv) analyzing the data using methods set forth in the protocol; and (v) comparing results from the data analysis with the hypothesis to see whether the hypothesis was proven or disproven. *See* Jackson Depo. at 156:25-158:19. However, in reviewing the materials Dr. Jackson relied upon in formulating her opinions, it does not appear that she followed the scientific method to its conclusion.

Dr. Jackson testified that the articles on which she relied to establish her opinion on general causation do not, by themselves, present valid scientific conclusions and are capable, at most, of generating hypotheses on the issue of causation. *See id*. at 195:7-20, 201:17-202:10, 266:23-270:2. In her report, Dr. Jackson opines that Prozac may be responsible for "an inherent destabilizing effect" in people, that Prozac ingestion "is accompanied by reduced firing rates of serotonin and dopamine neurons, which is "believed to account for akathisia and other side effects which can lead to aggression and suicide," and that SSRIs "likely increase the risk of chronic and/or recurrent depression or anxiety." **[*54]** Report at 46. At her deposition, however, Dr. Jackson testified that each of these statements, upon which she bases her conclusion, is merely a statement of hypothesis. *See* Jackson Depo. 323:4-324:1. By relying on articles that only present hypotheses, and extrapolating from those articles to state hypotheses of her own, which she then uses to form the basis for her conclusion, Dr. Jackson has not moved beyond the first step in the scientific method upon which she purportedly relied. Untested hypotheses do not form the basis for admissible scientific opinions. *See* *Norris, 397 F.3d at 887*; *Truck Ins. Ex., 360 F.3d at 1212*; *In re: Breast Implant Litigation, 11 F.Supp.2d at 1228*.

5. Chain-of-Events Causation

[20] *See* Hill, A.B., *The Environment and Disease: Association or Causation*?, 58 Proceedings of the Royal Society of Medicine (1965) at 295-300, attached at Exhibit O to Def't. Mem. In this article, Hill states that, *after a statistically significant association between the drug and the adverse event is shown*, factors to be considered in causation analysis include: 1) strength of association, 2) consistency of the association, 3) specificity of the association, 4) temporal relation between exposure and the adverse event, 5) biological gradient (dose-response relationship), 6) biological plausibility, 7) coherent with generally known facts about the disease, 8) experimental results, and 9) analogy.

Rather than focusing directly on the causal link between Prozac and the homicide and suicide that was the outcome of interest in this case, Dr. Jackson instead employed a chain-of-events methodology. She opined that patients ingesting Prozac may develop akathisia, and that the ″unrelenting psychic distress of akathisia″ may make suicide and/or homicide an ″attractive solution[].″ Report at 39. In other words, her causation methodology looks at the causal relationship, if any, between [*55] Prozac and akathisia, and then looks at the causal relationship, if any, between akathisia and homicide or suicide. From those two steps, Dr. Jackson infers that Prozac may cause a person to commit homicide or suicide.

In *Miller v. Pfizer, Inc., 196 F.Supp.2d 1062, 1080 (D.Kan. 2002)*, *aff'd*, *356 F.3d 1326 (10th Cir. 2004)*, the court found that this type of indirect, chain-of-events causation was not a generally-accepted scientific methodology. The plaintiffs in *Miller* alleged that the ingestion of Zoloft, an SSRI, caused their thirteen-year-old son to commit suicide. Similar to Dr. Jackson, the plaintiff's proffered expert was ″an accomplished researcher in neuropsychopharmacology, and his credentials are not in dispute.″ *Id. at 1065*. Indeed, he had ″made important contributions to the history of psychiatry and many significant clinical contributions.″ *Id*. The plaintiffs' expert relied heavily on case reports and his own studies and calculations, and disavowed the need for randomized controlled trials and epidemiological studies. *See id. at 1067*.

In examining the ″general acceptance″ of the proffered expert's methodology, the *Miller* court stressed that its focus was not on the expert's [*56] credentials or on the conclusion reached, but solely on the technique he used to reach his conclusion. *Id. at 1075*. In its attempt to resolve the Daubert issue in its case, the *Miller* court retained the services of two independent experts to advise it. *See id. at 1065*. Based on the testimony of its appointed independent experts, the court found that the expert's methodology failed, concluding that:

> generally accepted methodology in this case required [the expert] to consistently test the strength of association between SSRI drugs and suicide (the outcome of interest) -- rather than the association between SSRI drugs and akathisia (which is purported to be part of the chain of events that lead to suicide, rather than an independent outcome).

Id. at 1080. The court's independent experts also explained that ″determining the strength of association 'requires at least two groups of subjects, one exposed to the agent of interest [Zoloft], the other not exposed, so that rates of the outcome event (suicide) can be determined and compared.″ *Id*. As discussed earlier, the studies on which Dr. Jackson relied to establish causation had no controls.

Dr. Jackson's methodology fails for reasons similar [*57] to those stated in *Miller*. The failure of her methodology is somewhat amplified by the fact that, in addition to failing the *Daubert* factors of general acceptance in the scientific community and following scientific standards (i.e., failure to follow the Hill standard and the scientific method, as discussed earlier), it falls short on another Daubert factor as well. Dr. Jackson admits that she never attempted to publish the methodology she employed to generate her opinion in any peer reviewed journal, nor did she seek to have her methodology peer-reviewed by any other means such as presentation at a scientific meeting. *See* Jackson Depo. at 55:17-56:3. Instead, her opinion and the methodology enabling it were created strictly for this litigation.

6. Plaintiff's Response

Rather than directly addressing the legitimate criticisms leveled at Dr. Jackson's methodology,

Plaintiff instead ridiculed Defendant for seeking to prevent the admission of her testimony, relied on the admission of testimony by other experts using other methodologies in other cases, and sought to bolster her report through argument of counsel and studies not relied upon by Dr. Jackson in completing her report. Plaintiff [*58] also chose not to call Dr. Jackson to testify at the Daubert hearing, merely filing a short affidavit from her instead. This affidavit, filed two days prior to the hearing, spared Dr. Jackson the rigors of cross examination, but also did little to refute the criticism of her methodology.

Because, as the Court has previously stated, it is not ruling on the validity of the conclusions put forth by Dr. Jackson, but rather on the reliability of the proffered expert and the basis for her report, the supplemental materials and arguments put forth by Plaintiff's counsel (but not considered by Dr. Jackson in preparing her report) provide little assistance in this analysis. The bottom line is that the Court has determined that the methodology Dr. Jackson used to arrive at her general causation opinion is unreliable, so that, even if others using a reliable methodology arrived at a similar conclusion, her opinion still fails the *Daubert* test.

During her deposition, Dr. Jackson testified that all of the articles and other material on which she relied to support her opinion are cited in her Report. *See* Jackson Depo. at 18:19-19:1, 30:6-11, 36:22-37:19. She explicitly stated that, because she did [*59] not rely on materials that were not cited in her report, Defendant's counsel did not need to be concerned about reviewing any additional materials. *Id*. at 37:11-19. Dr. Jackson's assurances are in keeping with the requirements of *Fed. R. Civ. P. 26(a)(2)(B)*, governing disclosures in expert witness reports. *Rule 26* requires an expert report to include "a complete statement of all opinions to be expressed and the basis and reasons therefore," as well as "the data or other information considered by the witness in forming them." *Fed. R. Civ. P. 26(a)(2)(B)(i)* and *(ii)*. Plaintiff's Response Memorandum [Doc. 75] cites at least 15 articles and other materials that Dr. Jackson did not cite in her Report and upon which she admittedly did not rely in forming her opinion. Many of these articles raise issues not even discussed in Dr. Jackson's report. Plaintiff spends almost half of his Response Memorandum discussing these new materials, essentially asking the Court to find Dr. Jackson's methodology reliable because of the information used in counsel's attempt to supplement and bolster her report. *See* Pl. Resp. Mem. [Doc. 75] at 5-13. All of the materials cited by Plaintiff in his Response were [*60] available to Dr. Jackson at the time she wrote her report, but she did not rely on them. These materials cannot now be used, after the fact, to rehabilitate a flawed report. [21]

Clearly, the timeframe that Dr. Jackson had for completing her Report was tight. The initial email to Dr. Jackson giving her the assignment [*61] listed the tight deadline as the only "con" against taking the job. *See* E-mail from Karin Shepherd to Dr. Jackson regarding *Rimbert v. Eli Lilly* (dated September 5, 2007), attached as Exhibit C to Def't Mot. [22] In her deposition, Dr. Jackson cited time constraints several times as the reason that she did not read a particular article or pursue a particular line of inquiry. *See, e.g.*,

[21] It appears that Plantiff's counsel's attempts to rehabilitate his expert using materials extraneous to her Report began prior to filing his Response Brief. Plaintiff relies heavily on the "Juurlink article" in his Response Brief. He writes of Dr. Jackson citing the article in her deposition, giving the impression that it was something that she relied on in reaching her opinion, or that it was at least within her field of knowledge. However, Dr. Jackson had not read the article prior to completing her report, or even prior to her initial deposition. In fact, Plaintiff's counsel gave her the article after the first session of her deposition, which was adjourned early because Dr. Jackson was fatigued. *See* Jackson Depo. at 244:12-23. It was not until her second deposition, conducted nearly two months after her initial one, that she cited the article provided to her by counsel.

[22] Although the email listed the due date of the Report as September 24, 2007, less than three weeks from the date of the email, the final report was actually dated November 1, 2007. Report at 52.

Jackson Depo. at 60:23-61:21, 256:16-19. While the Court is sympathetic to the difficulty of completing a thorough report on such a complex subject in a short amount of time, even by a purported expert in the field, nonetheless, under *Fed. R. Civ. P. 26(a)(2)(B)*, an expert report must be judged on its merits. A defendant is entitled to rely on a report and the materials cited therein in evaluating the strength of its case, choosing which defenses to employ, selecting its own experts and guiding their approach, conducting its deposition of the expert, and preparing its Daubert challenge. Not only are materials not considered by the expert in preparing her report largely irrelevant to the Court's evaluation of her methodology, but allowing a party, at this stage, to combat a Daubert challenge using such [*62] materials, including those which raise new theories and issues, would unfairly encumber the opponent in its trial preparation and presentation of its Daubert challenge.

C. Specific Causation

Even if Dr. Jackson's general causation methodology were found to be reliable, the Court finds that her testimony should be disallowed because her specific causation methodology is fatally flawed as well. In reaching her opinion on specific causation, Dr. Jackson claims to have employed a methodology known as differential diagnosis. *See* Jackson Depo. at 261:19-25. The differential diagnosis method requires that potential causes for an outcome (in this case, a homicide and suicide) be ruled in as possibilities using valid scientific evidence, and then, using a process of elimination, be ruled out, if possible, using valid scientific evidence. *Id.* at 262:4-263:12. Differential diagnosis, if properly applied, is a valid technique for determining specific causation. *See Goebel v. Denver and Rio Grande W. R.R. Co., 346 F.3d 987, 998 (10th Cir. 2003)*. [*63] Of course, for a differential diagnosis to be admissible to demonstrate specific causation, a valid showing of general causation must have first been made. *See id.* The material question, therefore, is not whether Dr. Jackson employed a valid technique, but whether, even assuming a valid showing of general causation, she employed that technique in a reliable manner.

In conducting a differential diagnosis, "the underlying premise…is that there is an established connection between certain possible causes and a condition or symptom-then all of the established causes are ruled out but one." *Bitler v. A.O. Smith Corp., 391 F.3d 1114, 1124 n.6 (10th Cir. 2004)*(quoting Saltzberg, et al., *Federal Rules of Evidence Manual* at 702-35 (8th ed. 2002)). In undertaking such an analysis, an expert certainly need not unconditionally exclude each possible cause. That would present much too high of a burden, especially in cases such as this one, in which multiple factors can combine to cause a single outcome. Instead, an expert must simply follow "a process of eliminating possible causes as improbable until the most likely one is identified." *Bitler, 391 F.3d at 1124*. They must present "more than mere [*64] possibility," but rather "must eliminate other possible sources as highly improbable, and must demonstrate that the cause identified is highly probable." *Id.* This requires that the expert "provide objective reasons for eliminating alternative causes." *Id.*

As discussed in the Background section of this opinion, at the time of these tragic events, Mr. Rimbert was laboring under a multitude of significant life stressors, including the failure of his 42 year marriage, rejection by his family, severe financial setbacks, substantial chronic health problems, and boredom and isolation in his retirement. Dr. Jackson identified these risk factors in her report, and testified that the combination of Mr. Rimbert's depression and his life circumstances could explain the ultimate outcome "without Prozac being involved." Jackson Depo. at 148:22-149:3. She also agreed that the idea that the homicide-suicide was triggered by a combination of Mr. Rimbert's life circumstances

″could be a reasonable interpretation″ even in the absence of Prozac. *Id*. at 128:1-14. In her report, Dr. Jackson stated that Mr. Rimbert appeared to be at moderately high risk for suicide prior to the initiation of Prozac, and she [*65] testified that his life stressors were a complete explanation for the deaths of him and his wife. *See* Report at 32, Jackson Depo. at 110:1-9. She then admitted that she could not rule out Mr. Rimbert's depression and significant life stressors, by themselves, as the cause of the deaths. *See* Jackson Depo. at 149:12-22.

The problem with Dr. Jackson's differential diagnosis is not that she was unable to completely rule out the combination of Mr. Rimbert's depression and myriad life stressors as the trigger for the deaths in the absence of Prozac. That would be asking her to meet a higher burden than the law requires. Instead, the problem is that, not only did she fail to provide objective reasons for eliminating this alternative explanation as highly improbable, but she also failed to demonstrate that the cause she identified (Prozac) was highly probable.

Ultimately, almost everything in Dr. Jackson's specific causation opinion is hypothetical and speculative, except for her conclusion. She wrote that ″it is unknown″ whether Mr. Rimbert may have been among the small percentage of Caucasians who are poor metabolizers of Prozac, that he ″may have″ been vulnerable to a rise in blood and brain [*66] levels of Prozac, that he ″may have″ experienced an interaction between Prozac and the Zantac that he could possibly have been taking for heartburn, or that he ″may have″ experienced a drug interaction between Prozac and one of the other medications he was taking (because, despite the fact that none of the medications he was taking are potent disruptors of the 3A4 enzyme, ″there remains the possibility″ that the agents in those medications nonetheless interfered with each other). Report at 48. Similarly, Prozac ″may have″ exacerbated aspects of Mr. Rimbert's pre-existing medical conditions, he ″may have″ been especially sensitive to the initial dose, or he ″may have″ had an atypical accumulation of Prozac in the brain. *Id*. at 49-50. Rather than concluding that the postmortem femoral blood sample that revealed ″normal″ levels of Prozac in Mr. Rimbert made her hypotheses about abnormal accumulation less likely, Dr. Jackson instead speculated that ″it is possible″ that Mr. Rimbert's blood levels of Prozac ″may have″ been reduced significantly by smoking, or that it is ″possible″ that he could have stopped taking Prozac in the days before the shootings, or that ″another possibility″ is [*67] that Mr. Rimbert's pre-existing medical conditions increased his sensitivity to the effects of Prozac so that even normal levels of Prozac in the bloodstream could have produced lethal effects. *Id*. at 50. As Dr. Jackson conceded, each of these potential factors and mechanisms were only hypothetical or speculative. *See* Jackson Depo. at 325-335.

The Court's concern over Dr. Jackson's reliance on hypotheses and speculation to support her specific causation opinion is exacerbated by her apparent failure to take into consideration seemingly relevant facts or to explain the basis for her refusal to consider them. Necessarily central to Dr. Jackson's causation opinion that Prozac-induced akathisia led Mr. Rimbert to kill his wife and himself is that his akathisia developed as a result of taking Prozac. Dr. Jackson testified to her opinion that, after taking Prozac, Mr. Rimbert developed akathisia on top of his depression. Jackson Depo. at 151:7-12. Akathisia is a condition consisting of two components: (1) an inner, subjective feeling of restlessness; and (2) an observable, outward manifestation of psychomotor activation, such as hand-wringing. *Id*. at 144:13-22. In her deposition, Dr. Jackson [*68] agreed that if a patient described himself as feeling ″restless,″ that would satisfy the first criteria of akathisia, and if he said that he ″can't keep still,″ that would satisfy the second aspect.

See id. at 249:6-250:6. On August 18, 2003, before he was prescribed Prozac, Mr. Rimbert filled out an instrument called the Zung depression scale in Dr. Hochstadt's office. *See* Hochstadt depo. Rat 39-40; Copy of Mr. Rimbert's Zung Depression instrument, attached as Ex. P to Def't Mem. (hereinafter "Rimbert's Zung instrument"). In filling out the instrument, Mr. Rimbert indicated that "I am restless and can't keep still" some of the time. Hochstadt Depo. at 44:10-13; Rimbert's Zung instrument. In addition to the answer containing the diagnostic criteria for akathisia found on the Zung depression instrument, Mr. Rimbert's restlessness and inability to keep still on August 18, 2003, prior to ingesting Prozac, was also noted by Dr. Hochstadt in his notes. *See* Hochstadt Depo. at 37:19-38:14 (discussing notation that Mr. Rimbert's physical examination showed a "depressed, anxious-appearing gentleman," which, for Dr. Hochstadt would indicate "somebody who probably is not sitting still in their **[*69]** seat, who may be wringing their hands, they may have sweaty palms, they may have difficulty carrying on a conversation in a direct fashion"). Dr. Jackson does not recall seeing Mr. Rimbert's Zung depression scale instrument as part of the record that she reviewed, although she does not dispute its contents, and admits that she likely did not consider it in formulating her opinion. *See* Jackson Depo. at 83-85. Not only did Dr. Jackson not take into account evidence that Mr. Rimbert exhibited akathisic symptoms prior to ingesting Prozac, but she testified that, if she had considered that evidence, "it would in no way influence the opinions which I've expressed in my report." *Id*. at 84:13-18. This appears to be directly contrary to *Bitler's* requirement to provide objective reasons for eliminating alternative causes of the outcome in question.

Additionally, on the Zung depression scale that he completed prior to beginning his Prozac regimen, Mr. Rimbert indicated that "I feel that others would be better off if I were dead" some of the time. Hochstadt Depo. at 45:13-16; Rimbert's Zung instrument. Dr. Jackson agreed that this answer indicates the presence of suicidal ideation. Jackson Depo. **[*70]** at 87:15-24. Dr. Jackson testified that one of the things she relied on in reaching her opinion that Prozac was responsible for the deaths of Mr. and Mrs. Rimbert is that he did not have suicidal thinking prior to taking Prozac. *See id*. at 260:16-261:1, 285:15-20. In doing so, she failed to review and take into account Dr. Hochstadt's deposition (which was taken August 15, 2007, weeks prior to Dr. Jackson receiving her assignment) and the Zung depression scale completed by Mr. Rimbert that appears to contradict her formulation of specific causation. Not only did she not provide an objective reason to avoid taking this contradictory evidence into consideration, but she testified that, even though she did not review Mr. Rimbert's responses on the Zung instrument, her opinion would not have changed no matter what Mr. Rimbert's objective responses on that scale had indicated. *See id*. at 86:19-87:14. A methodology that inexplicably ignores material facts and relies only on selective evidence does not lead to a reliable opinion. Dr. Jackson did not properly apply the differential diagnosis methodology as laid out in *Bitler*, her opinion relies on assumptions (lack of akathisia and suicidal **[*71]** ideation prior to ingestion of Prozac) that are questionable at best, and she provides no explanation for ignoring contrary evidence. Her specific causation opinion is therefore unreliable, and will be excluded.

CONCLUSION

IT IS THEREFORE ORDERED that Defendant's *Motion to Renew Dispositive and* Daubert *Motions or, in the Alternative, to Certify Orders for Interlocutory Appeal* [Doc. 136] is GRANTED and Defendant's *Motion to Exclude* Expert Testimony of Dr. Grace Jackson [Doc. 58] is GRANTED.

/s/ Judith C. Herrera

JUDITH C. HERRERA

UNITED STATES DISTRICT JUDGE

DeVito v. Smithkline Beecham Corp.

United States District Court for the Northern District of New York

November 29, 2004, Decided ; November 29, 2004, Filed

Civil Action # 02-CV-0745 (NPM/DRH)

Reporter
2004 U.S. Dist. LEXIS 27374; 2004 WL 3691343

MICHAEL DEVITO, Plaintiff -against- SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, Defendant.

Prior History: *In re Paxil Prods. Liab. Litig., 296 F. Supp. 2d 1374, 2003 U.S. Dist. LEXIS 23465 (J.P.M.L., 2003)*

Disposition: Defendant's motions to preclude plaintiff's expert testimony and for summary judgment dismissing complaint granted.

Core Terms

causation, warnings, symptoms, withdrawal, discontinuation, reliability, qualifications, admissibility, scientific, labeling, qualify, pharmacology, adequacy, witnesses, issues, Aff, deposition testimony, deposition, internal quotation marks, summary judgment motion, prescription drug, expertise, pharmacy, expert testimony, citations, clinical, offering, requires, training, causes

Case Summary

Procedural Posture

Plaintiff, a former consumer of Paxil medication, alleged claims against defendant manufacturer for fraud, negligence, strict liability, breach of express warranty, and breach of implied warranty. The manufacturer moved to exclude the testimony of three proffered expert witnesses, pursuant to *Fed. R. Evid. 702* and moved for summary judgment, should the proffered testimony be held inadmissible.

Overview

The consumer alleged that the manufacturer knew of the hazardous side effects of Paxil and either concealed, misrepresented, or failed to warn of them, causing his injuries in withdrawing from the use of the medication. Following the conclusion of discovery, the manufacturer asserted that all of the consumer's evidence of both general and specific causation failed to meet the gateway requirement for admissibility. One proffered expert was a pharmacist with a Master's Degree in nutrition; a second was a former psychiatrist of plaintiffs; and the third was his treating nurse practitioner. The court found that, while the psychiatrist had expert credentials, he had made no differential diagnosis of the consumer's alleged injury, but merely taken the consumer's word that the withdrawal was problematic. The pharmacist was not qualified to testify about the warning labels of the drug, and the nurse practitioner admitted she had no expertise in the medical field. Without any evidence of causation the manufacturer was entitled to summary judgment in its favor.

Outcome

The manufacturer's motion to exclude the testimony of the three proffered expert witnesses was granted, and the motion for summary judgment was granted.

LexisNexis® Headnotes

Torts > ... > Elements > Causation > Causation in Fact

Torts > Products Liability > General Overview

Torts > Products Liability > Theories of Liability > Breach of Warranty

HN1 Under New York law, whether an action is pleaded in strict products liability, breach of warranty, or negligence, the plaintiff in a products liability case bears the burden of establishing that a defect in the product as a substantial factor in causing the injury.

Torts > Business Torts > Fraud & Misrepresentation > General Overview

Torts > ... > Causation > Proximate Cause > General Overview

HN2 Common law fraud requires a showing of proximate causation, such that the injury is the natural and probable consequence of the defrauder's misrepresentation or the defrauder ought reasonably to have foreseen that the injury was a probable consequence of the fraud.

Torts > ... > Elements > Causation > Causation in Fact

HN3 In the context of Paxil litigation, the general causation question is limited to whether discontinuation from Paxil is capable of causing dizziness, agitation, anxiety, nausea, etc. Specific causation, on the other hand, focuses on whether a plaintiff can prove that the symptoms came from Paxil.

Evidence > Types of Evidence > Testimony > General Overview

Evidence > ... > Testimony > Examination > Judicial Interrogation

Evidence > ... > Testimony > Expert Witnesses > General Overview

Evidence > Admissibility > Expert Witnesses

Evidence > Admissibility > Expert Witnesses > Helpfulness

Evidence > ... > Testimony > Expert Witnesses > Qualifications

HN4 There is a two-part inquiry in deciding the admissibility of expert evidence. First, in accordance with *Fed. R. Evid. 702*, the court should admit specialized expert testimony if the witness is qualified as an expert by knowledge, skill, experience, training or education and his testimony will assist the trier of fact to understand the evidence or to determine a fact in issue. Second, in the form of an opinion or otherwise, the court must insure that (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case. *Fed. R. Evid. 702*. In other words, whether an expert witness' opinion is ultimately admissible depend on the reliability and relevance of the proffered testimony.

Evidence > ... > Testimony > Expert Witnesses > General Overview

Evidence > Admissibility > Expert Witnesses

HN5 A district court must act as a gatekeeper to exclude invalid and unreliable expert testimony. The gatekeeping obligation applies whether the proposed expert testimony is based upon scientific knowledge, technical, or some other specialized knowledge. *Fed. R. Evid. 702*.

Evidence > ... > Procedural Matters > Preliminary Questions > General Overview

Evidence > Relevance > Exclusion of Relevant Evidence > Confusion, Prejudice & Waste of Time

Evidence > Admissibility > Expert Witnesses > Daubert Standard

HN6 Under *Fed. R. Evid. 403*, relevant evidence may be excluded if its probative value is substantially outweighed by the danger of unfair

prejudice, confusion of issues, or misleading the jury. Expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it. Because of that risk, the judge in weighing possible prejudice against probative force under *Rule 403* exercises more control over experts than over lay witnesses. The proponent of expert evidence must establish admissibility under *Fed. R. Evid. 104(a)* by a preponderance of the proof. That burden is the same regardless of whether the issue is the qualifications of a person to be a witness, or the admissibility of the evidence itself.

Evidence > ... > Testimony > Expert Witnesses > General Overview

HN7 In assessing expert qualifications, liberality and flexibility in evaluating qualifications should be the rule; a proposed expert should not be required to satisfy an overly narrow test of his or her own qualifications. So long as the expert stays within the reasonable confines of the subject area, the expert can fairly be considered to possess the ″specialized knowledge″ required by *Fed. R. Evid. 702*.

Evidence > Admissibility > Scientific Evidence > Standards for Admissibility

Evidence > ... > Testimony > Expert Witnesses > General Overview

Evidence > Admissibility > Expert Witnesses > Daubert Standard

HN8 The United States Supreme Court articulates four factors pertinent to determining the reliability of an expert's reasoning or methodology: (1) whether the theory or technique relied on has been tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and the existence and maintenance of standards controlling the technique's operation; and (4) whether the theory or method has been generally accepted by the scientific community.

Evidence > Admissibility > Scientific Evidence > Standards for Admissibility

Evidence > ... > Testimony > Expert Witnesses > General Overview

Evidence > Admissibility > Expert Witnesses

Evidence > Admissibility > Expert Witnesses > Daubert Standard

HN9 When evaluating the admissibility of nonscientific expert testimony, the standard under *Fed. R. Evid. 702* is a liberal and flexible one, and the factors outlined in Daubert are merely guidelines in aiding a court's reliability determination.

Evidence > ... > Testimony > Expert Witnesses > General Overview

Evidence > Admissibility > Expert Witnesses

HN11 Ordinarily once a court finds a witness qualified as an expert, the next issue is the admissibility of that witness' opinion testimony.

Evidence > ... > Testimony > Expert Witnesses > General Overview

Evidence > ... > Testimony > Expert Witnesses > Qualifications

HN10 A witness must satisfy the court that he has a certain amount of knowledge, skill, experience, training or education in the relevant field before he can be deemed an expert.

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Judges: NEAL P. McCURN, Senior District Judge.

Opinion by: NEAL P. McCURN

Opinion

MEMORANDUM-DECISION AND ORDER

I. Preclusion Motion

A. Standard for Admissibility of Expert

1. Deborah L. Sweeney

a. Qualified?

2. Kevin W. George. M.D

3. James T. O'Donnell

a. General Causation

i. Qualified?

ii. Reliability of Testimony?

b. Specific Causation

c. Warnings

i. Qualified

ii. Reliability of Testimony?

II. Summary Judgment Motion

Introduction

"Between 1987 and 1997, the percentage of Americans being treated for depression more than tripled nationwide[.]" Shankar Vedantam, *Report Shows Big Rise in Treatment for Depression,* WASH. POST, Jan. 9, 2002, at A01. In December [*2] 1996, plaintiff Michael DeVito became one of those Americans. At that time, his primary care physician prescribed Paxil, a selective serotonin reuptake inhibitor ("SSRI"). Mr. DeVito takes Paxil to this day, despite attempts through the years to discontinue. DeVito claims that he cannot discontinue taking Paxil because he has become "dependent" upon it. Affidavit of Robert E. Glanville (Oct. 20, 2003), exh. A thereto (Complaint) at 2, P 9. More specifically, plaintiff alleges that he has been unable to stop taking Paxil due to what he characterizes as "withdrawal reactions" or "dependency/withdrawal syndrome," which according to plaintiff "includes, but [is] not limited to, dizziness, nausea, shaking, electrical-like shocks and horrible dreams." Id. at 2, PP 7 and 6.

In this lawsuit plaintiff alleges five causes of action against the manufacturer of Paxil, defendant Smithkline Beecham Corporation d/b/a Glaxo Smithkline ("Glaxo"): (1) fraud; (2) negligence; (3) strict liability; (4) breach of express warranty; and (5) breach of implied warranty. There is a great deal of overlap among these five causes of action. The thrust of plaintiff's complaint is that Glaxo failed to adequately [*3] warn of "Paxil's addictive qualities and dependency/withdrawal characteristics[.]" Id. at 6, P 19; see also id. at 3, P 11b); at 7, P 25; and at 8, P 33. [1]

[*4] Discovery is complete and Glaxo is now moving for summary judgment pursuant to *Fed. R. Civ. P. 56*. Pursuant to *Fed. R. Evid. 702* and *Daubert* v. Merrell Dow Pharms., Inc., *509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993)*, Glaxo is also moving to preclude the testimony of the three witnesses whom plaintiff is proffering as experts. The court will address Glaxo's motion to preclude first because if any or all of the proffered testimony is inadmissible, then that could significantly impact Glaxo's summary judgment motion in terms of the admissible proof before the court. See *Toole v. Toshin Co, Ltd., No.*

[1] The present action, which has been referred to as a "tag-along action," is one of a number throughout the country wherein plaintiffs are alleging that Glaxo knew of the hazardous side effects of Paxil and either concealed, misrepresented or failed to warn of them. See In re Paxil Products Liability Litigation, 296 F. Supp. 2d 1374 (Judicial Panel on Multidistrict Litigation 2003). In mid-February 2004, this court was advised that the Judicial Panel on Multidistrict Litigation ("the Panel) had conditionally transferred this action to the United States District Court for the Central District of California for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407." Glaxo moved to vacate that conditional transfer as it pertained to the present case. When plaintiff did not respond, on June 15, 2004, the Panel vacated that conditional transfer as it relates to Mr. DeVito.

00-CV-821S, 2004 WL 2202580, at *4 (W.D.N.Y. Sept. 29, 2004) (granting defense motion to preclude testimony of plaintiff's expert and declining to consider his report on summary judgment motion).

I. Preclusion Motion

Each of the five causes of action which plaintiff alleges requires him to prove causation. ***HN1*** ″Under settled New York law, whether the action is pleaded in strict products liability, breach of warranty or negligence, the plaintiff in a products liability case [*5] bears the burden of establishing that a defect in the product as a substantial factor in causing the injury.″ Prohaska v. Sofamor. S.N.C., 138 F. Supp. 2d 422, 434 (W.D.N.Y. 2001) (internal quotation marks and citation omitted). ***HN2*** Common law fraud likewise ″requires a showing of proximate causation, such that the injury is the natural and probable consequence of the defrauder's misrepresentation or … the defrauder ought reasonably to have foreseen that the injury was a probable consequence of his fraud.″ Cyber Media Group, Inc. v. Island Mortgage Network, Inc., 183 F. Supp. 2d 559, 580 (E.D.N.Y. 2002) (internal quotation marks and citation omitted). To establish causation here, plaintiff DeVito ″must offer admissible testimony regarding *both general causation,″ i.e.* that Paxil can cause the type of symptoms of which plaintiff complains when attempting to discontinue that drug, ″*and specific causation,″ i.e.* that Paxil actually caused DeVito's alleged symptoms upon discontinuation of Paxil. See Amorvianos v. National Railroad Passenger Corporation, 303 F.3d 256, 268 (2d Cir. 2002) (citation omitted) (emphasis added); see also [*6] Blanchard v. Eli Lilly & Co., 207 F. Supp. 2d 308, 314 (D.Vt. 2002) (citations omitted) (″Plaintiffs … must prove both general and specific causation in order to prevail on their claim, that is, that Prozac is capable of causing and in fact did cause the deaths in this case.″). ***HN3*** In the context of Paxil litigation, ″the general causation question is limited to whether discontinuation from Paxil is *capable* of causing dizziness, agitation, anxiety, nausea, etc.″ In re Paxil Litigation, 218 F.R.D. 242, 249 (C.D. Cal. 2003). Specific causation, on the other hand, focuses on whether a plaintiff can ″prove that [his] symptoms came from Paxil, as opposed to, for example, the relapse of the underlying illness or the consumption or discontinuation of other drugs.″ Id.

To establish causation, plaintiff DeVito seeks to offer the testimony of three ″expert″ witnesses: (1) Mr. John T. O'Donnell, a pharmacist with a Master's Degree in nutrition; (2) Dr. Kevin W. George, a former psychiatrist of plaintiffs; and (3) Ms. Deborah Sweeney, plaintiff's treating nurse practitioner. Glaxo is seeking to ″preclude … [these] experts from offering any opinion [*7] that: (I) Paxil causes substance dependence, or is either addictive or habit-forming; or (ii) that plaintiff is addicted to Paxil or has developed substance dependence as a result of taking it.″ Memorandum of Law in Support of Glaxosmithkline's Motion to Preclude Plaintiffs Experts' Testimony Pursuant to Fed. R. Evid. 702 and Daubert (″Def. Preclude Memo.″) at 4. In preparation for trial, each of these witnesses has been deposed and Mr. O'Donnell has provided an ″expert″ report on plaintiff s behalf. Apart from these witnesses, plaintiff proffers no other causation evidence.

To support his theory that Paxil is defective due to an inadequate warning, plaintiff is relying solely upon the deposition testimony and ″expert″ report of Mr. O'Donnell. Glaxo argues for the preclusion of ″his warnings 'opinions'″ because O'Donnell is not qualified to testify on that issue and even if he were, ″his opinions are neither reliable nor scientific.″ Def. Preclude Memo. at 24.

A. Standard-for Admissibility of Expert Evidence

HN4 There is a two-part inquiry in deciding the admissibility of expert evidence. First, in accordance with Fed. R. Evid. 702 [*8] , ″the court should admit specialized expert testimony if

the witness is 'qualified as an expert by knowledge, skill, experience, training or education' and his testimony 'will assist the trier of fact to understand the evidence or to determine a fact in issue.'" Nora Beverages, Inc. v. Perrier Group of America, Inc., 164 F.3d 736, 746 (2d Cir. 1998) (quoting Fed. R. Evid. 702); see also Kass v. West Bend Company, 2004 U.S. Dist. LEXIS 22217, No. 02-CV-3719, 2004 WL 2475606, at *4 (E.D.N.Y. Nov. 4, 2004) (citation omitted) ("As a threshold matter, the court must examine [the witness'] qualifications to testify about alternative ? designs.") Second, "in the form of an opinion or otherwise," the court must insure that "(1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." Fed. R. Evid. 702. In other words, whether an expert witness' "opinion is ultimately admissible depend on the reliability and relevance of the proffered testimony." Kass, 2004 U.S. Dist. LEXIS 22217, 2004 WL 2475606, [*9] at *5.

In this regard, the Supreme Court has instructed the by now oft-cited rule that ***HN5*** a district court must act as "a gatekeeper to exclude invalid and unreliable expert testimony." Bonton v. City of New York, 2004 U.S. Dist. LEXIS 22105, No. 03 Civ. 2833, 2004 WL 2453603, at *2 (S.D.N.Y. Nov. 3, 2004) (citation omitted). This gatekeeping obligation applies whether the proposed expert testimony is based upon scientific knowledge, "technical," or some other "specialized" knowledge. See Kumho Tire Co. v. Carmichael, 526 U.S. 137, 141, 143 L. Ed. 2d 238, 119 S. Ct. 1167, 1171 (1999) (citing Fed. R. Evid. 702). As with other types of evidence, the court must also bear in mind that ***HN6*** under Rule 403, even relevant evidence "may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of issues, or misleading the jury." Fed. R. Evid. 403. In Daubert the Supreme Court soundly reasoned that "expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it. Because of this risk, the *judge* in weighing possible prejudice against probative force [*10] under Rule 403 … *exercises more control over* experts than over lay witnesses." Daubert, 509 U.S. at 595, 113 S. Ct. at 2798 (quotation marks and citation omitted) (emphasis added). Finally, it should be noted that "the proponent of expert evidence must establish admissibility under Rule 104(a) of the Federal Rules of Evidence by a preponderance of the proof." Bonton, 2004 U.S. Dist. LEXIS 22105, 2004 WL 2453603, at *2 (citing Bourjaily v. United States, 483 U.S. 171, 175-76, 97 L. Ed. 2d 144, 107 S. Ct. 2775 (1987)). This burden is the same regardless of whether the issue is the "qualifications of a person to be a witness, …, or the admissibility of the evidence" itself. Fed. R. Evid. 104(a). In the present case, this requires plaintiff Devito to prove by a preponderance of the evidence that each of the three witnesses whom he is proposing to call as an expert qualify as such; *and* that the proposed testimony of each is admissible.

HN7 "In assessing expert qualifications, 'liberality and flexibility in evaluating qualifications should be the rule; the proposed expert should not be required to satisfy an overly narrow [*11] test of his own qualifications.'" Kass, 2004 U.S. Dist. LEXIS 22217, 2004 WL 2475606, at *4 (quoting Lappe v. American Honda Motor Co., Inc., 857 F. Supp. 222, 227 (N.D.N.Y. 1994) aff d 101 F.3d 682 (2d Cir. 1996)). "So long as the expert stays within the 'reasonable confines of his subject area,' the expert can fairly be considered to possess the 'specialized knowledge' required by Rule 702." Id. (quoting Lappe, 857 F. Supp. at 227) (other citation omitted).

HN8 "In Daubert, the Supreme Court articulated four factors pertinent to determining the reliability of an expert's reasoning or methodology: (1) whether the theory or technique relied on has been tested; (2) whether the theory or technique has been subjected to peer review and publication; (3)

whether there is a known or potential rate of error and the existence and maintenance of standards controlling the technique's operation; and (4) whether the theory or method has been generally accepted by the scientific community." Id. (citing Daubert, 509 U.S. at 593-94, 113 S. Ct. at 2796-97). "These factors do not, however, constitute a 'definitive checklist or test. [*12] '" Id. (quoting Daubert, 509 U.S. at 593, 113 S. Ct. at 2796). "Rather, they are intended to be applied flexibly, depending on the particular circumstances of the particular case at issue." Id. (citing Kumho Tire, 526 U.S. at 150, 119 S. Ct. at 1175).

In Kumho, the Supreme Court recognized that ***HN9*** "when evaluating the admissibility of non-scientific expert testimony, the standard under Rule 702 is a liberal and flexible one, and the factors outlined in Daubert are merely guidelines in aiding a court's reliability determination." Houlihan v. Marriott International, Inc., 2003 U.S. Dist. LEXIS 17382, No. 00 Civ. 7439, 2003 WL 22271206, at *3 (S.D.N.Y. Sept. 30, 2003) (citing Kumho, 526 U.S. at 151, 119 S. Ct. at 1175). "For example, in some cases, reliability concerns may focus on personal knowledge or experience rather than strict scientific methods." Id. (citation omitted). Regardless of which criteria a court applies to assess the admissibility of expert testimony, "the Supreme Court has made clear that the district court has a 'gatekeeping function' under Rule 702 -- is charged with 'the task of ensuring that an expert's testimony [*13] both rests on a reliable foundation and is relevant to the task at hand.'" Amorgianos, 303 F.3d at 265 (quoting Daubert, 509 U.S. at 597, 113 S. Ct. 2786) (other citation omitted). Finally, it should be noted that "'the gatekeeping inquiry must be tied to the facts of a particular case[.]'" Id. at 266 (quoting Kumho Tire, 526 U.S. at 150, 119 S. Ct. at 1175).

1. Deborah L. Sweeney

a. Qualified?

Glaxo's motion to preclude the testimony of Ms. Sweeney [2] requires little if any analysis. Glaxo is moving to preclude her testimony because it does not believe she is qualified to testify as an expert. Additionally, Glaxo contends that "her proposed opinion lacks a reliable scientific foundation." Def. Preclude Memo. at 26. Plaintiff did not bother to respond to this aspect of Glaxo's motion. This lack of response amounts to a concession by plaintiff that the court should exclude Ms. Sweeney's testimony. Cf. Green v. Doukas, 2001 U.S. Dist. LEXIS 8861, No. 97 CIV.8288CMGAY, 2001 WL 767069, at *8 (S.D.N.Y. June 22, 2001) (granting motion to preclude expert testimony because "plaintiff's failure to oppose the motion suggests . [*14] .. it has merit[]"). Accordingly, the court grants Glaxo's motion to the extent it is seeking preclusion of Ms. Sweeney's testimony. SeeAmaker v. Coombe, 2003 U.S. Dist. LEXIS 8790, No. 96 Civ. 1622, 2003 WL 21222534, at *6 (S.D.N.Y. May 27, 2003) (granting motion to preclude where plaintiff defaulted); see also Martinez v. Sanders, 2004 U.S. Dist. LEXIS 10060, No. 02 Civ. 5624, 2004 WL 1234041, at * 3 (S.D.N.Y. June 3, 2004) (because plaintiff did not respond to motion, court granted same on "default" theory) (and cases cited therein).

[*15] ***2. Kevin W. George, M.D.***

Glaxo also seeks to preclude the testimony of Dr. Kevin George. Dr. George is a psychiatrist who saw Mr. DeVito in consultation twice -- once on November 2, 2001 and again on December 13, 2001. Glanville Aff., exh. G thereto at 51 and 76.

[2] During her deposition Ms. Sweeney unequivocally testified, "I'm not a physician. I'm not a nurse practitioner." Glanville Aff., exh H thereto at 123. She holds an associates' degree in nursing, a bachelor of science degree in health and human services, and a nurse practitioner's degree." Id. at 12, 17, 35-36. Thus, to refer to Ms. Sweeney as "Doctor Sweeney, as plaintiff does throughout his expert disclosure, is not only a misstatement but directly contradicts Sweeney's own testimony. Plaintiff's tendency to exaggerate or overstate certain things, as will be seen, is not limited to the qualifications of his experts.

Glaxo is not challenging Dr. George's qualifications, but rather the nature of his testimony. Glaxo is seeking to exclude Dr. George's testimony because he ″has expressly disavowed all of the opinions that plaintiff ascribed to him in plaintiff's expert disclosure.″ Def. Preclude Memo. at 25. Further, even if Dr. George had not disavowed those opinions, Glaxo argues that his ″proposed testimony [is] inadmissible because it lacks any reliable scientific foundation.″ Id.

Plaintiff's response focuses almost exclusively on Dr. George's qualifications, which are not in dispute. As to the opinions which plaintiff attributes to Dr. George, the sum total of plaintiffs response is that any alleged ″shortcomings″ in that testimony go to weight and credibility, and not to admissibility. Memorandum of Law in Opposition to Defendant's Motion to Preclude Plaintiff's Experts (″Pl. Opp'n Preclude″) at 5. The court **[*16]** disagrees. As will be seen, Dr. George's purported opinion testimony does not have simply a few ″shortcomings.″ It has glaring holes in terms of reliability, not the least of which is Dr. George's unequivocal deposition testimony disavowing that he made the opinions which plaintiff claims he did.

In his expert disclosure plaintiff specifically identifies Dr. George as an ″expert″ whom he intends to call at the time of trial. Glanville Aff., exh. E thereto at 1. According to plaintiff's expert disclosure, Dr. George will testify as follows:

> that in his opinion, within a degree of reasonable medical certainty, … [1] the plaintiff is experiencing withdrawal reactions from the drug Paxil and that each time the plaintiff attempts to 'wean' himself off of the drug or to lower the dosage of the drug, the plaintiff experiences said withdrawal; 2) … the plaintiffs withdrawal signs and symptoms are a result of the plaintiff ingesting Paxil; and 3) … the plaintiff has sustained injury in that he has been unable to discontinue the use of Paxil and has been caused to suffer the signs and symptoms of the withdrawal syndrome associated with the use and attempted discontinuance **[*17]** of Paxil.

Glanville Aff., exh E thereto. Dr. George is confining his opinions to how Paxil allegedly *effected* plaintiff DeVito - not whether Paxil is *capable generally* of causing the symptoms of which DeVito complains. Therefore, although the plaintiff did not specify the purpose for which he is offering Dr. George's testimony, presumably it is being offered on the issue of specific causation.

As noted earlier, ***HN11*** ordinarily once a court finds a witness qualified as an expert, the next issue is the admissibility of that witness' opinion testimony. Here, however, it appears that each of the opinions which plaintiff attributes to Dr. George have been expressly disavowed in his deposition. Dr. George was asked point blank whether he had formed any of the three opinions quoted above, and whether he was prepared to testify to same. Each time he answered no. See Glanville Aff., exh. G thereto at 88-91. Obviously, if Dr. George has not formed the opinions which plaintiff is ascribing to him, necessarily he has no foundation, scientific or otherwise, for same. Accordingly, the court excludes the opinion testimony outlined above which plaintiff is attributing to Dr. George.

[*18] Even if Dr. George had not expressly disavowed the opinions set forth above, the court still must exclude his testimony. The crux of each of these opinions is that plaintiff DeVito has ″withdrawal reactions,″ or ″withdrawal signs and symptoms″ caused when he attempts to discontinue or taper below a certain dosage of Paxil. Glanville Aff., exh. E thereto. Dr. George's deposition testimony did not so state such. To be sure, Dr. George did testify that he used ″Paxil withdrawal″ as a ″*label* to capture what [DeVito] was describing that he had been experiencing.″

Id., exh. G thereto at 59 (emphasis added). When later in his deposition Dr. George was pressed as to whether or not he diagnosed plaintiff ″as suffering from Paxil withdrawal[,]″ he, reiterated that he ″*applied that label* to describe the symptoms that [DeVito] reported in relation to tapering Paxil.″ Id. at 102 (emphasis added).

There is an obvious difference between labeling a symptom which a patient describes and actually diagnosing that person. Significantly, Dr. George did *not* diagnosis plaintiff with Paxil withdrawal. Perhaps that is because ″Paxil withdrawal is not a formal diagnosis within **[*19]** DMS-IV[.]″ Id. at 94. (″The DSM-IV is the Diagnostic and Statistical Manual, the fourth revision of it, that psychiatrists generally base their diagnoses on.″ Id.) And, ″there is no criteria for diagnosing somebody with Paxil withdrawal.″ Id. at 60. For example, there are no ″objective tests or assessments,″ aside from skin inspection for signs of sweating, ″that could have been done to determine whether those reports [by DeVito] were genuine[.]″ Id. at 62. So, Dr. George simply took plaintiffs description of his symptoms at ″face value,″ and made no attempt to determine whether [DeVito's] report of those symptoms was genuine[.]″ Id. at 62 and 79.

In light of the foregoing, even if Dr. George were inclined to testify that Paxil specifically caused the symptoms which plaintiff claims it did, there is no foundation for this testimony. What is particularly revealing in this regard is Dr. George's candor when asked: ″Have you ever made any determination as to why Mr. DeVito's tapering off of Paxil may be taking longer than some of your other patients?'″ Id. at 100. Dr. George replied, ″I had *no scientific way,* …, of explaining why he was having **[*20]** such difficulty tapering off Paxil.″ Id. (emphasis added).

Further, plaintiff DeVito saw Dr. George in the latter's capacity as a treating psychiatrist. Thus, as is plain from Dr. George's deposition, he was concerned primarily with the symptoms of which plaintiff complained, not determining the underlying cause. See *Munafo v. Metropolitan Transportation Authority, 2003 U.S. Dist. LEXIS 13495, Nos. 98 CV-4572, 00-CV-0134, 2003 WL 21799913, at * 19 (E.D.N.Y. Jan. 22, 2003)*. Had Dr. George been focusing on the underlying cause, undoubtedly he would have performed a differential diagnosis, which ″typically includes a physical examination, clinical tests, and a thorough case history.″ *Zwillinger v. Garfield Slope Housing Corp., 1998 U.S. Dist. LEXIS 21107, No. CV 94-4009, 1998 WL 623589, at * 19 (E.D.N.Y. Aug. 17) 1998)* (citations omitted). But, Dr. George did not. Without a differential diagnosis, specific causation cannot be established. See id. (″To establish specific causation, other possible causes for the symptoms experienced by plaintiff should be excluded by performing a 'differential diagnosis.'″)

3. James T. O'Donnell

Glaxo argues that the court must preclude O'Donnell's **[*21]** testimony for two reasons. First, he is not qualified as an expert as to the issues upon which he is being asked to opine -- general and specific causation and the adequacy of the Paxil warnings. Second, even if he does qualify as an expert, Glaxo contends that the court should preclude his opinions because they lack the requisite scientific foundation and are otherwise unreliable. Plaintiff responds that O'Donnell's ″experience and credentials are impressive[,]″ whether the issue is his qualifications to testify as an expert on causation or as an expert on warnings. Pl. Preclude Memo. at 4. Plaintiff further responds that regardless of whether O'Donnell is opining on causation or warnings, any alleged ″shortcomings″ in that testimony go to ″weight and credibility, and not [to] … admissibility.″ Id. at 5 (citation omitted).

Plaintiff DeVito is offering O'Donnell's testimony on three separate issues, which require different areas of expertise. The court will examine O'Donnell's qualifications as to each.

a. General Causation

Glaxo offers a host of reasons as to why O'Donnell ″is not an 'expert' on scientific issues concerning general *or* specific causation″ [*22] with respect to SSRIs or Paxil. Def. Preclude Memo. at 7 (emphasis added). All of these reasons have merit.

i. Qualified?

This is not the first court to be confronted with the issue of whether Mr. O'Donnell is qualified to give an expert opinion here. In *Newton v. Roche Laboratories. Inc., 243 F. Supp. 2d 672 (W.D.Tex. 2002)*, the court found that he was *not* qualified to render an opinion on general causation. *Id. at 679*. There, the parents of a 16 year old girl claimed that Accutane, a prescription acne medication manufactured by the defendant, caused or precipitated the onset of their daughter's schizophrenia. In much the same way plaintiff DeVito is offering O'Donnell's testimony here, the plaintiffs in Newton offered O'Donnell as an expert ″to testify regarding general causation, *i.e.,* that Accutane is pharmacologically capable of causing schizophrenia.″ *Id. at 677*. After outlining a number of ways in which O'Donnell's qualifications were lacking, the court expressly found that he was not qualified to render such an opinion.

To support that conclusion, the Newton court relied upon O'Donnell's deposition [*23] testimony, which is substantially similar to his deposition testimony in this case. For example, O'Donnell testified in Newton, as he did here, that ″he has never earned an M.D., a Ph.D., or any degree in pharmacology.″ *Id. at 677*; see also O'Donnell Dep'n at 24-25 and 53. Yet, he ″still holds himself out as a 'doctor' and a pharmacologist[.]″ Id. As in Newton, ″O'Donnell … [continues to] grant[] himself the title of 'doctor' in reliance upon his Pharm.D degree, [which] he conceded in his deposition that in the majority of pharmacy schools, that … degree is 'an entry-level degree' that pharmacists must have to … even practice pharmacy.″ *Id. at 677 n. 2* (citation omitted); see also O'Donnell Dep'n at 24-25. In contrast, to obtain a degree in pharmacology usually three or four years of graduate school is required. O'Donnell Dep'n at 25-26. O'Donnell did get a graduate degree, but it was not in pharmacology. O'Donnell's formal education consists of a four year degree in pharmacy and a Master's Degree in clinical nutrition. Id. at 27.

In addition to questioning O'Donnell's background generally, the Newton court [*24] pointed out his ″lack [of] appropriate pharmacological training relevant to the issues″ therein, *i.e.* ″Accutane, Vitamin A, schizophrenia, or psychosis[.]″ *Id. at 678*. The same may be said here. There is no factual basis upon which this court can find that O'Donnell is an expert regarding SSRIs generally, not to mention Paxil or discontinuation of Paxil. Indeed, as his deposition testimony shows, O'Donnell's asserted expertise on these subjects is non-existent. See id. at 21, 24; 38-40; and 45.

Given that SSRIs are a fairly recently developed class of drugs, understandably they were not the subject of O'Donnell's course work as an undergraduate, or when getting his Master's Degree in nutrition. Id. at 21 and 24. Since that time, O'Donnell has done nothing to advance his own knowledge as to SSRIs generally or Paxil in particular. When directly asked if he had ″done any clinical research whatsoever relating to antidepressants,″ O'Donnell replied that he had not. Id. at 38. He responded the same way when asked if he had ″done any scientific research concerning Paxil or SSRI antidepressants[.]″ Id. at 39. Moreover, O'Donnell conceded that the first time [*25] he ″reviewed … scientific literature in connection with Paxil discontinuation symptoms[]″ was for this case. Id. at 40-41.

This is the sort of ″litigation-drive expertise″ which courts have eschewed. To illustrate, the court in *Mancuso v. Consolidated Edison Co., 967*

F. Supp. 1437, 1443, reasoned that it could not ″help but conclude that [plaintiff's expert] was not in fact an expert … when he was hired by the plaintiffs, but that he subsequently attempted, with dubious success, to qualify himself as such by selective review of the relevant literature.″ This appears to be an apt description of what Mr. O'Donnell attempted to do in the present case.

The court stresses that it is no single factor which is dispositive of whether O'Donnell qualifies as an expert on the issue of general causation. Rather, it is the cumulative effect of the foregoing which convinces the court that O'Donnell lacks the lack of relevant ″knowledge, skill, experience, training or education″ to testify as an expert on the issue of general causation *vis-a-vis* the discontinuation of Paxil. As he admitted, O'Donnell is *not* a pharmacologist. Therefore, he cannot, as he does in his ″expert report,″ opine [*26] to a ″reasonable pharmacological certainty,″ that plaintiff is experiencing ″withdrawal toxicity reactions from Paxil[.]″ O'Donnell Rep. Clearly, allowing a pharmacist/nutritionist such as O'Donnell to testify in that way would run afoul of the rule that an expert must stay ″within the reasonable confines of his subject area[.]″' *Kass, 2004 U.S. Dist. LEXIS 22217, 2004 WL 2475606*, at *2475606, at *4 (internal quotation marks and citations omitted). Simply put, the court agrees with the court's comment in Newton that ″plaintiff's attempts to present O'Donnell as an expert pharmacologist [is] … an extremely bold stretch.″ *Newton, 243 F. Supp. 2d at 679*. [3]

[*27] ***ii. Reliability of Testimony?***

O'Donnell's lack of education, training and background as to Paxil becomes even more apparent when viewed in terms of the opinions which he has rendered in this case. That is so because a ″court's evaluation of qualifications is not always entirely distinct from the court's evaluation of reliability.″*Pearson v. Young, 2002 U.S. Dist. LEXIS 26256, No. CIV-99-1559-F, 2002 WL 32026157, at * 3 (W.D.Okla. Jan. 17, 2002)*.

O'Donnell's opinion as to causation is that ″DeVito is experiencing withdrawal toxicity reactions from Paxil, and indeed, each time he attempts to wean or lower the dosage, he again experiences such infinity [sic].″ Glanville Aff., exh. E thereto. O'Donnell states that when plaintiff's dosage of Paxil is lowered, he suffers from the following ″withdrawal signs and symptoms[:] anxiety, jitery [sic], agitation, nausea, drowsiness, generalized discomfort and vertigo[.]″ O'Donnell Report at 2. ″For this opinion to be admissible, O'Donnell must have *a reliable scientific basis* to support not only (1) a casual relationship between″ Paxil and the enumerated side-effects, ″but also (2) his assertion that [Paxil] will produce these [*28] side-effects.″ See *Newton, 243 F. Supp. 2d at 679* (emphasis added). O'Donnell's report and deposition testimony are void of a scientific basis to support either of those assertions.

In terms of publications, O'Donnell testified that he was the editor of a non-peer reviewed book entitled ″Drug Injury Liability, Analysis and Prevention.″ Id. at 98-99. That book contained a mere six sentences on SSRIs, including the two

[3] O'Donnell's insistence on holding himself out as a pharmacologist, see O'Donnell Dep'n at 54, ignores at least one fundamental distinction between pharmacology and pharmacy - a distinction which is critical here. ″Pharmacology can be fairly described as the study of the effect of drugs on living organisms. Pharmacy, on the other hand, is the profession of preparing and dispensing drugs.″ Newton, 243 F. Supp. 2d at 677, n.1. It is self-evident that there is a vast difference in the education, experience and skill necessary to obtain degrees in these two different fields.

Apparently O'Donnell recognizes this distinction because in Newton he ″admitted … that from approximately 1982 to 1985, he intentionally and falsely advertised that he possessed a doctorate in pharmacology in an attempt to attract more interest from lawyers for his consulting expert business.″ Id. at 677, n.3 (citation omitted). He made that same admission in this deposition herein. O'Donnell Dep'n at 28-31. O'Donnell did change this advertisement because, in his words, it was ″incorrect.″ Id. at 29. This court cannot overlook what at best appears to be a serious lapse in judgment, however.

sentences on Paxil. Id. at 99. Given that minimal reference to SSRIs, it is not surprising that that book contains nothing about discontinuation symptoms. See id. It further appears that he has performed absolutely no research regarding Paxil, much less its discontinuation. Id. at 38-39. What is more, O'Donnell has done no scientific or clinical research of any kind for almost two decades. The last time he did any such research was in he ″early '80s as part of a pharmacology lab sabbatical,″ where he was looking at vitamins and critical care drugs used in Intensive Care Units. Id. at 36.

In light of the foregoing, to allow plaintiff to rely upon Mr. O'Donnell's opinions as to general causation clearly would violate Daubert's [*29] ″requirement that the expert testify to scientific knowledge -- conclusions support by good grounds for each step in the analysis[.]″' *Amorgianos, 303 F.3d at 267* (citations and quotation marks omitted).

b. Specific Causation

It stands to reason that if Mr. O'Donnell lacks (which he does) the qualifications to testify as to general causation, he lacks the qualifications to testify as to specific causation. His opinion as to specific causation suffers from the same infirmities, detailed above, as to general causation. Accordingly, the court finds that Mr. O'Donnell does not have the requisite qualifications to testify as to specific causation; and even if he did, his opinions in that regard are unreliable.

c. Warnings

Glaxo contends that because O'Donnell ″lacks any pertinent qualifications[,]″ Def. Memo. at 14, he should not be allowed to testify that in his opinion the ″lack of … a precaution and warning about withdrawal risk and the need to taper [when discontinuing Paxil] renders the product defective due to an inadequate warning. See O'Donnell Report at 3. Plaintiff did not directly respond to this argument. Included [*30] in the list of highlighted credentials in plaintiff's memorandum of law is that Mr. O'Donnell ″is currently involved in the teaching of New Drug Development and Regulations[.] Pl. Opp'n Memo. at 2. However, plaintiff does not explain, or cite to any portion of O'Donnell's deposition explaining, how or why this position qualifies him to testify as an expert on warnings.

As with the other issues upon which plaintiff intends to offer O'Donnell's testimony, plaintiff baldly retorts that O'Donnell's ″extensive experience qualifies as specialized knowledge gained through experience, training, or education[.]″ Pl. Memo. at 4 (internal quotation marks and citations omitted). And, once again, he relies upon the argument that Glaxo's reasons to preclude O'Donnell's testimony regarding warnings should be saved for trial, *i.e.* they should be used to attack O'Donnell's credibility and the weight which the jury might give to his opinions regarding Paxil warnings.

i Qualified?

O'Donnell ″claims to be an expert in drug labeling[.]″ O'Donnell Dep'n at 90. Presumably he is including drug warnings within the province of this supposed expertise. In any event, to qualify as [*31] an expert it is not enough for a witness to simply declare that he is one. *Federal Rule of Evidence 702* requires more. As plaintiff acknowledged, ***HN10*** a witness must satisfy the court that he has a certain amount of ″knowledge, skill, experience, training or education[]″ in the relevant field before he can be deemed an expert. See *Nora Beverages, 164 F.3d at 746* (internal quotation marks and citation omitted). Close examination of O'Donnell's deposition testimony reveals that he is lacking in each of those areas when it comes to the subject of the adequacy of prescription drug warnings.

O'Donnell's claimed expertise admittedly is ″through experience,″ not through formal

education. O'Donnell Deposition at 90-92. His experience consists primarily of having attended continuing education ("CE") programs, where drug labeling was a topic. Id. Those CE programs were to satisfy his pharmaceutical and nutritionist CE requirements, however; and he was unable to elaborate on the substance of same. See id. Furthermore, O'Donnell has not consulted with any pharmaceutical company "concerning the labeling for any antidepressant[.]" Id. [*32] at 96. O'Donnell agrees "that the FDA [Food and Drug Administration] is the highest authority on how drugs are labeled in this country[,]" but he has also never consulted with them "concerning the labeling for any antidepressant. Id. For that matter, O'Donnell has not worked for or consulted with the FDA in any capacity. See Glanville Aff. at 9, P 39. Thus, O'Donnell's experience in this area is extremely limited.

Moreover, O'Donnell made two especially damaging concessions which seriously undermine the suggestion that he is an expert as to the adequacy of prescription drug warnings. O'Donnell readily agreed "that in assessing the adequacy of a label for a prescription drug, the expert rendering the opinion generally should be familiar with the clinical trials data on the drug as it relates to the side effect concerning which he is opining[.]" Id. at 192. Yet, O'Donnell frankly admitted that he had not reviewed any of the Paxil clinical trials data. See id. Similarly, O'Donnell conceded that "generally to reach a conclusion regarding the adequacy of a label for a prescription drug, the expert rendering the opinion should be familiar with at least a majority [*33] of the available medical literature on the drug as it relates to the side effect on which he is opining[.]" Id. at 193. Despite the foregoing, O'Donnell went on to testify that he has "not read the specific literature[]" relating to discontinuation symptoms of Paxil. Id. 193 and 45. In fact, he has only read "abstracts" of articles. Id. at 46-47. Finally, Mr. O'Donnell has not lectured on, or written anything (peer reviewed or not) about, "Paxil discontinuation symptoms apart from [his] export [sic] report in this case[.]" Id. at 45. As the foregoing clearly shows, Mr. O'Donnell does not "employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field[,]" which here is the adequacy of prescription drug warnings and Paxil in particular. See *Kumho Tire, 526 U.S. at 152, 119 S. Ct. at 1176*.

Mr. O'Donnell may qualify as an expert in the fields of pharmacy or nutrition, but that is not the purpose for which his testimony is being offered here. Instead, his testimony is being offered on the adequacy of Paxil warnings. O'Donnell has never been drafter or been asked to draft a [*34] warning for any antidepressant, let alone for Paxil. Likewise, he has not done any research or written any publications on prescription drug warnings. Thus, whether judged in terms of his education or experience, does not rise to the level of "expertise … that the jury would expect from a bona fide warnings expert." See Robertson v. Norton, 148 F.3d 905, 907 (8th Cir. 1998) (internal quotation marks omitted).

In sum, O'Donnell is being called upon to testify regarding the adequacy of the Paxil warning, an issue which clearly is outside the "reasonable confines of his subject areas," which are pharmacy and nutrition. See *Kass, 2004 U.S. Dist. LEXIS 22217, 2004 WL 2475606, at *4* (internal quotation marks and citations omitted). Therefore, because O'Donnell does *not* "possess the specialized knowledge required by *Rule 702*[,]" the court finds that he is not qualified as an expert on the issue of the adequacy of the Paxil warning. See id.

Ii. Reliability of Testimony?

Given the nature of the claims which plaintiff is alleging in this case, plainly there is a close relationship between excluding the causation opinion and excluding the warning opinions which [*35] are being offered by O'Donnell. *Miller v. Pfizer, Inc., 196 F. Supp. 2d 1062 (D. Kan. 2002)*,

aff'd on other grounds, *356 F.3d 1326* (l0th Cir. 2004), cert. denied, *125 S. Ct. 40, 160 L. Ed. 2d 201 (Oct. 4, 2004)*, provides a good example of how a decision to preclude causation "expert" testimony impacts upon a decision to also preclude warning testimony. The plaintiff parents in Miller were suing the manufacturer of Zoloft, another SSRI, alleging that it caused their son to commit suicide. Similar to the present case, the plaintiffs in Miller asserted state law claims for strict liability for marketing defects and misrepresentations, and negligence for failure to test and warn. The court held that an "eminent" psychiatrist and neuropsychopharmocologist's proposed testimony regarding general causation, *i.e.* that Zoloft causes, suicide, did not satisfy the Daubert criteria for admissibility because, in short, "he lacked sufficient expertise on the issue of suicide." *Id. at 1087* and *1088*. The Miller court, as is this court, was then confronted with the issue of whether that same doctor could qualify as an expert who would **[*36]** opine "that Zoloft labels do not adequately warn against the danger of SSRI-induced suicide." *Id. at 1088*. After finding that the doctor was not an expert on that issue, the court soundly reasoned, "if the jury will hear no evidence that [Paxil] causes [withdrawal symptoms/addictive], it cannot possibly conclude that [Paxil] labels do not adequately warn against the danger that [Paxil] causes [such condition.]" *Id. at 1089*. That reasoning applies with equal force here. Even if O'Donnell qualifies as a prescription drug warning expert, because neither O'Donnell nor Dr. George (plaintiffs only proof as to causation) qualify to testify about causation, the former's warning testimony "would essentially be irrelevant to any larger issues in the case." See id. Accordingly, there is no need to analyze whether O'Donnell's opinions, as to warnings pass muster under Daubert.

In short, plaintiff DeVito has not sustained his burden of proving by a preponderance of the evidence that Mr. O'Donnell is qualified to render an opinion as to general causation, specific causation, or the adequacy of Paxil warnings. Even if O'Donnell could somehow be **[*37]** deemed to have the requisite "specialized knowledge" to testify as to any or all of those issues, "courts do not have to credit opinion evidence connected to data 'only by the *ipse dixit* of the expert.'" *Prohaska, 138 F. Supp. 2d at 438* (quoting *General Elec. Co. v. Joiner, 522 U.S. 136, 118 S. Ct. 512, 139 L. Ed. 2d 508 (1997)*). That is all O'Donnell has to rely upon; simply because he offers an opinion which he claims to be valid, plaintiff assumes it is so. This court will not, however.

For the reasons set forth above, the court grants in its entirety Glaxo's motion to preclude the testimony of Mr. O'Donnell; Dr. George; and Ms. Sweeney.

II Summary Judgment Motion

The court assumes familiarity with the Supreme Court's trilogy of cases clarifying the governing legal standards on summary judgment motions, and sees no need to repeat those standards herein. See *Anderson v. Liberty Lobby Inc., 477 U.S. 242, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986)*; *Celotex Corp. v. Catrett, 477 U.S. 317, 91 L. Ed. 2d 265, 106 S. Ct. 2548 (1986)*; and *Matsushita Elec. Industr. Co. v. Zenith Radio Corp., 475 U.S. 574, 89 L. Ed. 2d 538, 106 S. Ct. 1348 (1986)*.

It is an understatement to say that the wholesale exclusion **[*38]** of the testimony of O'Donnell, George and Sweeney significantly impacts plaintiff DeVito's case.

As discussed at the outset causation is a necessary element of each of the five causes of action which plaintiff is alleging herein. Because plaintiff's only causation evidence has been excluded, it necessarily follows that Glaxo is entitled to summary judgment in its favor. See *Kass, 2004 U.S. Dist. LEXIS 22217, 2004 WL 2475606* (after granting motion to exclude testimony of plaintiff's claimed expert regarding the feasibility of alternative designs, court granted defense summary

judgment motion because plaintiff could not satisfy the critical element of a design defect cause of action); and *Zwillinger, 1998 U.S. Dist. LEXIS 21107, 1998 WL 623589* (where plaintiff claimed that her exposure to defendants' carpeting causes her to develop immunotoxicity syndrome, court granted summary judgment in defendants' favor after excluding the of doctor's testimony, which was plaintiffs only causation evidence).

To conclude, the court hereby GRANTS the motion by Smithkline Beecham Corporation d/b/a Glaxo Smithkline, to preclude the testimony of James O'Donnell; Dr. Kevin George; and Ms. Deborah Sweeney. The court further **[*39]** GRANTS the motion by Smithkline Beecham Corporation d/b/a Glaxo Smithkline for summary judgment pursuant to *Fed. R. Civ. P. 56* dismissing all of plaintiff Michael DeVito's claims as against it.

IT IS SO ORDERED.

Syracuse, New York

Nov 29, 2004

Neal G. McCurn

Senior U.S. District Court Judge

CIVIL JUDGMENT

Decision by Court. This action came to trial or hearing before the Court.

The issues have been tried or heard and a decision has been rendered.

IT IS ORDERED AND ADJUDGED

That the Motion to Preclude the testimony of James O'Donnell, Dr. Kevin George and Ms. Deborah Sweeney is granted and further ordered that the Motion for Summary Judgment dismissing all plaintiff Michael DeVito's claims against Smithkline Beecham Corporation d/b/a GlaxoSmithkline is granted.

All of the above pursuant to the Order of the Honorable Neal P. McCurn, dated the 29th day of November, 2004.

NOVEMBER 29, 2004